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## **Approvers**

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Test	One	Two

## **Document History**

Revision	Date (YYYY-MM-DD)	Description of Changes
Test	One	Two

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2		<u>2</u>
3	<u>10'</u>	<u>Z</u>
	3.1 <u>10'</u>	<u>Z</u>
	3.2	7

## **Associated Products**

Product Name	Product Model	Part Number	Catalog Number
Rogahn PLC	aut	48184	architecto
Marks-Murphy	quos	73335	et
Bashirian, Bechtelar and Boyle	non	59185	totam

## **General Safety and Performance Requirements**

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	CHAPTER I GENERAL REQUIREMENTS		
	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.		
	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.		
	Manufacturers shall establish, implement, document and maintain a risk management system.		
N/A	Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall		
3.(a)	establish and document a risk management plan for each device;		
	identify and analyse the known and foreseeable hazards associated with each device;		
3.(c)	estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;		
3.(d)	eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;		
3.(e)	evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, the benefit-risk ratio and risk acceptability; and		
3.(f)	based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.		
	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority		
	eliminate or reduce risks as far as possible through safe design and manufacture;		
4.(b)	where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and		
	provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.		
N/A	Manufacturers shall inform users of any residual risks.		
	In eliminating or reducing risks related to use error, the manufacturer shall		
, ,	reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and		

	Standards Evidence o					
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance		
5.(b)	give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the					
	medical and physical conditions of intended users (design for lay, professional, disabled or other users).					
6.	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the					
	patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by					
	the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been					
	properly maintained in accordance with the manufacturer's instructions.					
7.	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their					
	intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and					
	humidity, taking account of the instructions and information provided by the manufacturer.					
	All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the					
	evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal					
	conditions of use.					
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3.(b)	identify and analyse the known and foreseeable hazards associated with each device;					
3.(c)	estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable					
	misuse;					
3.(d)	eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;					
3.(e)	evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on					
	hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, the					
	benefit-risk ratio and risk acceptability; and					
3.(f)	based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line					
	with the requirements of Section 4.					
4.	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety					
	principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturers shall manage risks					
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	In eliminating or reducing risks related to use error, the manufacturer shall			
5.(a)	reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and			
5.(b)	give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).			
	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.			
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7.	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.			
8.	All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal conditions of use.			
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No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and		
	give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).		
6.	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.		
	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.		
	All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal conditions of use.		
	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.		
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	evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, the benefit-risk ratio and risk acceptability; and		
3.(f)	based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.		

A. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority  4.(a) eliminate or reduce risks as far as possible through safe design and manufacture;  4.(b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and  4.(c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.  N/A Manufacturers shall inform users of any residual risks.  5. In eliminating or reducing risks related to use error, the manufacturer shall content of the device is intended to be used (design for patient safety), and  5. (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).  6. (i) The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer instructions.  7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and informa	No.	General Safety and Performance Requirements	Applicability		Evidence of
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5 ID MOEDITIV AND ANALYSE THE KNOWN AND TOPESPEADIE HAZAROS ASSOCIATED WITH EACH DEVICE.	/	identify and analyse the known and foreseeable hazards associated with each device;			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;		
3.(d)	eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;		
	evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, the benefit-risk ratio and risk acceptability; and		
. ,	based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.		
4.	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority		
4.(a)	eliminate or reduce risks as far as possible through safe design and manufacture;		
4.(b)	where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and		
4.(c)	provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.		
N/A	Manufacturers shall inform users of any residual risks.		
5.	In eliminating or reducing risks related to use error, the manufacturer shall		
	reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and		
5.(b)	give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).		
6.	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.		
	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.		
8.	All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal conditions of use.		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
1.	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way		- 1 1	•
	that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall			
	not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other			
	persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the			
	benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally			
	acknowledged state of the art.			
	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without			
	adversely affecting the benefit-risk ratio.			
	Manufacturers shall establish, implement, document and maintain a risk management system.			
	Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring			
	regular systematic updating. In carrying out risk management manufacturers shall			
	establish and document a risk management plan for each device;			
3.(b)	identify and analyse the known and foreseeable hazards associated with each device;			
3.(c)	estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable			
	misuse;			
3.(d)	eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;			
3.(e)	evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on			
	hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, the			
	benefit-risk ratio and risk acceptability; and			
3.(f)	based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line			
	with the requirements of Section 4.			
4.	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety			
	principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturers shall manage			
	risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting			
	the most appropriate solutions, manufacturers shall, in the following order of priority			
	eliminate or reduce risks as far as possible through safe design and manufacture;			
	where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be			
	eliminated; and			
	provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.			
	Manufacturers shall inform users of any residual risks.			
5.	In eliminating or reducing risks related to use error, the manufacturer shall			
	reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is			
	intended to be used (design for patient safety), and			
	give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the			
	medical and physical conditions of intended users (design for lay, professional, disabled or other users).			

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
6.	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the		търршен	Сотраниес
	patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by			
	the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been			
	properly maintained in accordance with the manufacturer's instructions.			
7.	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their			
	intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and			
	humidity, taking account of the instructions and information provided by the manufacturer.			
8.	All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the			
	evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal			
	conditions of use.			
	CHAPTER II REQUIREMENTS REGARDING PERFORMANCE, DESIGN AND MANUFAC	TURE		
9.	Performance characteristics			
	Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of			
	Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking			
	account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer			
	and in particular, where applicable			
9.1.(a)	the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and			
	reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range,			
	linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known			
	relevant endogenous and exogenous interference, cross- reactions; and			
, ,	the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive			
	value, likelihood ratio, expected values in normal and affected populations.			
9.2.	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the			
	manufacturer.			
9.3.	Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of			
	values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures			
	and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values			
	assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement			
	procedures.			
	The characteristics and performances of the device shall be specifically checked in the event that they may be affected when			
	the device is used for the intended use under normal conditions			
9.4.(a)	for devices for self-testing, performances obtained by laypersons;			
9.4.(b)	for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency			
	units, ambulances).			
10.	Chemical, physical and biological properties			
10.1.	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements		<u> </u>	
	referred to in Chapter I are fulfilled.			

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No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
N/A	Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical			•
	incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues,			
	cells, body fluids and micro-organisms), taking account of the intended purpose of the device.			
10.2.	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and			
	residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage			
	and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the			
	duration and frequency of exposure.			
	Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks			
	posed by substances or particles, including wear debris, degradation products and processing residues, that may be released			
	from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction			
	('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the			
	Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable			
	serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation			
	(EC) No 1907/2006 of the European Parliament and of the Council (2).			
	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional			
	ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.			
	Infection and microbial contamination			
	Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk			
	of infection to the user or, where applicable, other persons. The design shall			
	of fine-cubit to the user of, where applicable, other persons. The design shall		Standards	Evidence of
No.	General Safety and Performance Requirements	Applicability	Applied	<b>Compliance</b>
	) allow easy and safe handling;			
	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary			
11.1.(c	prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination			
	of the specimen.			
11.2.	Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to			
	ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the			
	manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition			
	or microbial state is damaged.			
11.3.	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated			
44.4	methods.			
11.4.	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.			
11.5.	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices			
	are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking			
	account of the method of sterilisation indicated by the manufacturer.			

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
11.6.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a		Applieu	Comphance
11.0.	non-sterile condition additional to the symbol used to indicate that devices are sterile.			
12.	Devices incorporating materials of biological origin			
N/A	Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the			
	processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be			
	carried out so as to provide safety for user or other person.			
12.(1)	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,			
	labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and			
	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).			
12.(2)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the			
	Registration,			
N/A	Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).			
N/A	In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of			
	validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain			
	devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or			
	when such elimination or inactivation process would compromise the performance of the device.			
13.	Construction of devices and interaction with their environment			
13.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the			
	connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use			
	applying to such combinations shall be indicated on the label and/or in the instructions for use.			
	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible			
13.2.(a)	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where			
	appropriate ergonomic features;			
13.2.(b)	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields,			
	external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic			
10.0 ( )	procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;			
13.2.(c)	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including			
40.0 (1)	gases, to which it is exposed during normal conditions of use;			
13.2.(d)	the risks associated with the possible negative interaction between software and the IT environment within which it operates			
10.0 ( )	and interacts;			
	the risks of accidental ingress of substances into the device;			
13.2.(f)	the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or			
	numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to			
12.2 ( )	perform the test or assay as intended;			
13.2.(g)	the risks of any foreseeable interference with other devices.			

No.	General Safety and Performance Requirements	<b>Applicability</b>		Evidence of
		rppiicubiity	Applied	Compliance
13.3.	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use			
	and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or			
10.1	use in association with flammable or explosive substances or substances which could cause combustion.			
13.4.	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely			
40.5	and effectively.			
13.5.	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.			
13.6.	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related			
	waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.			
13.7	The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and			
	manufactured in line with ergonomic principles, taking account of the intended purpose, users and the en vironmental			
	conditions in which the devices are intended to be used.			
	Devices with a measuring function			
14.1.	Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide			
	appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended			
	purpose of the device.			
14.2.	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions			
1.5	of Council Directive 80/181/EEC (1).			
	Protection against radiation			
15.1.	Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation			
	(intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.			
15.2.	When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as			
15.2.	far as possible be			
15 2 (a)	designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be			
15.2.(a)	controlled and/or adjusted; and			
15.2.(b)	fitted with visual displays and/or audible warnings of such emissions.			
15.3.	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed			
	information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of	:		
	reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and			
	performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.			
16.	Electronic programmable systems devices that incorporate electronic programmable systems and software that are devices in			
	themselves			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
16.1.	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves,		
	shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single		
	fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment		
16.2	of performance.		
16.2.	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk		
	management, including information security, verification and validation.		
16.3.	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be		
10.5.	designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the		
	screen) and the external factors related to their use (varying environment as regards level of light or noise).		
16.4.	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security		
	measures, including protection against unauthorised access, necessary to run the software as intended.		
17.	Devices connected to or equipped with an energy source		
17.1.	For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall		
	be adopted to eliminate or reduce as far as possible consequent risks.		
17.2.	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining		
	the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes		
	critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.		
17.3.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating		
	electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.		
17.4.	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro magnetic		
1,,,,,	interference such that is adequate to enable them to operate as intended.		
17.4.(1)	Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units		
	of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).		
17.5.	Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks		
	to the user, or other person both during normal use of the device and in the event of a single fault condition in the device,		
	provided the device is installed and maintained as indicated by the manufacturer.		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
18.	Protection against mechanical and thermal risks		
18.1.	Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.		
18.2.	Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses		
	inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices,		
	subject to any inspection and maintenance requirements as indicated by the manufacturer.		
18.3.	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances,		
	then appropriate protection means shall be incorporated.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
N/A	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure		
	and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as		
10.4	intended by the manufacturer.		
18.4.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from		
	vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.		
18.5.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the		
	noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless		
	the noise emitted is part of the specified performance.		
18.6.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person		
	has to handle, shall be designed and constructed in such a way as to minimise all possible risks.		
18.7.	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by		
	the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.		
N/A	The same information shall be given on moving parts and/or their housings where the direction of movement needs to be		
	known in order to avoid a risk.		
18.8.	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their		
	surroundings shall not attain potentially dangerous temperatures under normal conditions of use.		
19.	Protection against the risks posed by devices intended for self-testing or near-patient testing		
19.1.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform		
	appropriately for their intended purpose taking into account the skills and the means available to the intended user and the		
	influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The		
	information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in		
	order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient		
	testing, the information and the instructions provided by the manufacturer shall make clear the level of training,		
	qualifications and/or experience required by the user.		
	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to		
19.2.(a)	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after		
	appropriate training and/or information; and		
19.2.(b)	reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen,		
	and also in the interpretation of the results.		
19.3.	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended		
	user		
` ′	can verify that, at the time of use, the device will perform as intended by the manufacturer; and		
19.3.(b)	be warned if the device has failed to provide a valid result.		
9.	Performance characteristics		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable		
	the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross- reactions; and		
9.1.(b)	the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.		
	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.		
	Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.		
9.4.	The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions		
9.4.(a)	for devices for self-testing, performances obtained by laypersons;		
9.4.(b)	for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).		
10.	Chemical, physical and biological properties		
	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled.		
N/A	Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.		
	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.		

			Standards	Evidence of
No.	General Safety and Performance Requirements	Applicability		Compliance
10.3.	Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks			-
	posed by substances or particles, including wear debris, degradation products and processing residues, that may be released			
	from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction			
	('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the			
	Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable			
	serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation			
	(EC) No 1907/2006 of the European Parliament and of the Council (2).			
10.4.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional			
	ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended			
	to be used.			
11.	Infection and microbial contamination			
11.1.	Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the			
	risk of infection to the user or, where applicable, other persons. The design shall			
` ` ´	allow easy and safe handling;			
	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary			
	prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination			
	of the specimen.			
11.2.	Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to			
	ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the			
	manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition			
	or microbial state is damaged.			
11.3.	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated			
	methods.			
11.4.	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.			
11.5.	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices			
	are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking			
	account of the method of sterilisation indicated by the manufacturer.			
11.6.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a			
	non-sterile condition additional to the symbol used to indicate that devices are sterile.			
12.	Devices incorporating materials of biological origin			
N/A	Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the			
	processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be			
	carried out so as to provide safety for user or other person.			
12.(1)	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,			
	labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and			
	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
12.(2)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration,		
N/A	Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).		
N/A	In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.		
13.	Construction of devices and interaction with their environment		
13.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.		
13.2.	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible		
13.2.(a)	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;		
	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;		
13.2.(c)	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;		
13.2.(d)	the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;		
13.2.(e)	the risks of accidental ingress of substances into the device;		
13.2.(f)	the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended;	•	
13.2.(g)	the risks of any foreseeable interference with other devices.		
13.3.	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.		
13.4.	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.		
13.5.	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.		
13.6.	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
13.7	The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and		
	manufactured in line with ergonomic principles, taking account of the intended purpose, users and the en vironmental		
	conditions in which the devices are intended to be used.		
	Devices with a measuring function		
14.1.	Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide		
	appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended		
	purpose of the device.		
	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions		
	of Council Directive 80/181/EEC (1).		
	Protection against radiation		
15.1.	Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation		
	(intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended		
	purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.		
	When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as		
	far as possible be		
15.2.(a)	designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be		
	controlled and/or adjusted; and		
	fitted with visual displays and/or audible warnings of such emissions.		
15.3.	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed		
	information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of		
	reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and		
	performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.		
	Electronic programmable systems devices that incorporate electronic programmable systems and software that are devices in		
	themselves		
16.1.	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves,		
	shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single		
	fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment		
	of performance.		
	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and		
	manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk		
	management, including information security, verification and validation.		
	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be		
	designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the		
	screen) and the external factors related to their use (varying environment as regards level of light or noise).		
	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security		
	measures, including protection against unauthorised access, necessary to run the software as intended.		
17.	Devices connected to or equipped with an energy source		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
17.1.	For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.		
17.2.	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.		
17.3.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.		
17.4.	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro magnetic interference such that is adequate to enable them to operate as intended.		
17.4.(1)	Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).		
17.5.	Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.		
18.	Protection against mechanical and thermal risks		
18.1.	Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.		
18.2.	Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices,		
18.3.	subject to any inspection and maintenance requirements as indicated by the manufacturer.  Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.		
N/A	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.		
18.4.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.		
18.5.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.		
18.6.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.		
18.7.	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.		
N/A	The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
18.8.	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their		
	surroundings shall not attain potentially dangerous temperatures under normal conditions of use.		
19.	Protection against the risks posed by devices intended for self-testing or near-patient testing		
19.1.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform		
	appropriately for their intended purpose taking into account the skills and the means available to the intended user and the		
	influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The		
	information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in		
	order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient		
	testing, the information and the instructions provided by the manufacturer shall make clear the level of training,		
	qualifications and/or experience required by the user.		
	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to		
19.2.(a)	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after		
	appropriate training and/or information; and		
19.2.(b)	reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen,		
	and also in the interpretation of the results.		
19.3.	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended		
40.0 ( )	user the state of		
_ ` ′	can verify that, at the time of use, the device will perform as intended by the manufacturer; and		
	be warned if the device has failed to provide a valid result.		
9.	Performance characteristics		
9.1.	Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of		
	Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking		
	account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer		
0.4.()	and in particular, where applicable		
9.1.(a)	the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and		
	reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range,		
	linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known		
0.1 (b)	relevant endogenous and exogenous interference, cross- reactions; and		
9.1.(b)	the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive		
0.2	value, likelihood ratio, expected values in normal and affected populations.		
9.2.	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the		
9.3.	manufacturer.  Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of		
3.3.	values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures		
	and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values		
	assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement		
	procedures.		
	procedures.	İ	

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
9.4.	The characteristics and performances of the device shall be specifically checked in the event that they may be affected when		
	the device is used for the intended use under normal conditions		
	for devices for self-testing, performances obtained by laypersons;		
` '	for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency		
	units, ambulances).		
10.	Chemical, physical and biological properties		
10.1.	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance		
	requirements referred to in Chapter I are fulfilled.		
N/A	Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical		
	incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues,		
	cells, body fluids and micro-organisms), taking account of the intended purpose of the device.		
10.2.	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and		
	residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport,		
	storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to		
-	the duration and frequency of exposure.		
	Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks		
	posed by substances or particles, including wear debris, degradation products and processing residues, that may be released		
	from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction		
	('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the		
	Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable		
	serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation		
	(EC) No 1907/2006 of the European Parliament and of the Council (2).		
10.4.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional		
	ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended		
	to be used.		
	Infection and microbial contamination		
11.1.	Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the		
	risk of infection to the user or, where applicable, other persons. The design shall		
	allow easy and safe handling;		
	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary		
11.1.(c)	prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination		
<b>———</b>	of the specimen.		
	Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to		
	ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the		
	manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition		
	or microbial state is damaged.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
11.3.	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.		•
	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.		
11.5.	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices		
	are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking		
	account of the method of sterilisation indicated by the manufacturer.		
11.6.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a		
	non-sterile condition additional to the symbol used to indicate that devices are sterile.		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
12.	Devices incorporating materials of biological origin		
N/A	Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the		
	processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be		
	carried out so as to provide safety for user or other person.		
12.(1)	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,		
	labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and		
	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
12.(2)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the		
	Registration,		
	Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).		
N/A	In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of		
	validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain		
	devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or		
	when such elimination or inactivation process would compromise the performance of the device.		
13.	Construction of devices and interaction with their environment		
13.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the		
	connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use		
10.0	applying to such combinations shall be indicated on the label and/or in the instructions for use.		
	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible		
	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where		
	appropriate ergonomic features;		
13.2.(b)	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields,		
	external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic		
10.0 ( )	procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;		
` ′	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including		
	gases, to which it is exposed during normal conditions of use;		

No.	General Safety and Performance Requirements	Applicability		Evidence of
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	the risks associated with the possible negative interaction between software and the IT environment within which it operates			
	and interacts;			
	the risks of accidental ingress of substances into the device;			
13.2.(1)	the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or			
	numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended;			
12.2 (a)	the risks of any foreseeable interference with other devices.			
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13.3.	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use			
	and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or			
10.4	use in association with flammable or explosive substances or substances which could cause combustion.			
13.4.	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely			
10.5	and effectively.			
13.5.	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such			
10.C	a way that the interoperability and compatibility are reliable and safe.			
13.6.	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related			
	waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a			
10.7	result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.			
13.7	The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and			
	manufactured in line with ergonomic principles, taking account of the intended purpose, users and the en vironmental conditions in which the devices are intended to be used.			
1.4				
	Devices with a measuring function			
	Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide			
	appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended			
1.4.2	purpose of the device.			
14.2.	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).			
15.	Protection against radiation			
	Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation			
15.1.	(intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended			
	purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.			
15.2.	When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as			
	far as possible be			
	designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be			
	controlled and/or adjusted; and			
15.2.(b)	fitted with visual displays and/or audible warnings of such emissions.			
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No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
15.3.	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
16.	Electronic programmable systems devices that incorporate electronic programmable systems and software that are devices in themselves		
16.1.	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.		
16.2.	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.		
16.3.	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).		
16.4.	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.		
17.	Devices connected to or equipped with an energy source		
17.1.	For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.		
17.2.	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.		
17.3.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.		
17.4.	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro magnetic interference such that is adequate to enable them to operate as intended.		
17.4.(1)	Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).		
17.5. 18.	Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.  Protection against mechanical and thermal risks		

No.	General Safety and Performance Requirements	Applicability		Evidence of
110.	-	Applicability	Applied	Compliance
18.1.	Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.			
18.2.	Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses			
	inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices,			
	subject to any inspection and maintenance requirements as indicated by the manufacturer.			
18.3.	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.			
N/A	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure			
	and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as			
	intended by the manufacturer.			
18.4.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from			
	vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations,			
	particularly at source, unless the vibrations are part of the specified performance.			
18.5.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the			
	noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless			
	the noise emitted is part of the specified performance.			
18.6.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person			
	has to handle, shall be designed and constructed in such a way as to minimise all possible risks.			
18.7.	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by			
	the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.			
N/A	The same information shall be given on moving parts and/or their housings where the direction of movement needs to be			
	known in order to avoid a risk.			
18.8.	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their			
	surroundings shall not attain potentially dangerous temperatures under normal conditions of use.			
19.	Protection against the risks posed by devices intended for self-testing or near-patient testing			
19.1.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform			
	appropriately for their intended purpose taking into account the skills and the means available to the intended user and the			
	influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The			
	information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in			
	order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient			
	testing, the information and the instructions provided by the manufacturer shall make clear the level of training,			
	qualifications and/or experience required by the user.			
19.2.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to			
19.2.(a)	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after			
	appropriate training and/or information; and			
19.2.(b)	reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen,			
	and also in the interpretation of the results.			

No.		Applicability	Evidence of Compliance
	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user		
	can verify that, at the time of use, the device will perform as intended by the manufacturer; and		
19.3.(b)	be warned if the device has failed to provide a valid result.		
9.	Performance characteristics		
	Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable		
	the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross- reactions; and		
9.1.(b)	the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.		
9.2.	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.		
	Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
9.4.	The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions		
9.4.(a)	for devices for self-testing, performances obtained by laypersons;		
9.4.(b)	for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).		
10.	Chemical, physical and biological properties		
10.1.	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled.		
N/A	Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.		

No.	General Safety and Performance Requirements	Applicability		Evidence of
110.	General Safety and Performance Requirements	Applicability	Applied	Compliance
10.2.	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and			
	residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport,			
	storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to			
	the duration and frequency of exposure.			
10.3.	Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks			
	posed by substances or particles, including wear debris, degradation products and processing residues, that may be released			
	from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction			
	('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the			
	Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable			
	serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation			
	(EC) No 1907/2006 of the European Parliament and of the Council (2).			
10.4.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional			
	ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended			
	to be used.			
11.	Infection and microbial contamination			
11.1.	Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the			
	risk of infection to the user or, where applicable, other persons. The design shall			
	allow easy and safe handling;			
	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary			
11.1.(c)	prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination			
	of the specimen.			
11.2.	Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to			
	ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the			
	manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition			
	or microbial state is damaged.			
11.3.	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated			
	methods.			
11.4.	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.			
11.5.	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices			
	are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking			
	account of the method of sterilisation indicated by the manufacturer.			
11.6.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a			
<u> </u>	non-sterile condition additional to the symbol used to indicate that devices are sterile.			
12.	Devices incorporating materials of biological origin			
N/A	Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the			
	processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be			
	carried out so as to provide safety for user or other person.			

No.	General Safety and Performance Requirements	Applicability		Evidence of
		rppiicubiiity	Applied	Compliance
12.(1)	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,			
	labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and			
40 (0)	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).			
12.(2)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the			
DT / A	Registration,			
	Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).			
N/A	In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of			
	validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain			
	devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or			
4.0	when such elimination or inactivation process would compromise the performance of the device.			
13.	Construction of devices and interaction with their environment			
13.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the			
	connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use			
10.0	applying to such combinations shall be indicated on the label and/or in the instructions for use.			
	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible			
13.2.(a)	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where			
	appropriate ergonomic features;			
13.2.(b)	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields,			
	external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic			
	procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;			
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
13.2.(c)	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including			
	gases, to which it is exposed during normal conditions of use;			
13.2.(d)	the risks associated with the possible negative interaction between software and the IT environment within which it operates			
	and interacts;			
13.2.(e)	the risks of accidental ingress of substances into the device;			
13.2.(f)	the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or			
	numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to			
	perform the test or assay as intended;			
13.2.(g)	the risks of any foreseeable interference with other devices.			
13.3.	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use			
	and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or			
	use in association with flammable or explosive substances or substances which could cause combustion.			
13.4.	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.		
13.6.	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.		
13.7	The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the en vironmental conditions in which the devices are intended to be used.		
14.	Devices with a measuring function		
	Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended purpose of the device.		
14.2.	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).		
15.	Protection against radiation		
15.1.	Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.		
	When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be		
15.2.(a)	designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and		
15.2.(b)	fitted with visual displays and/or audible warnings of such emissions.		
15.3.	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.		
16.	Electronic programmable systems devices that incorporate electronic programmable systems and software that are devices in themselves		
	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.		
	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
16.3.	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be		
	designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the		
	screen) and the external factors related to their use (varying environment as regards level of light or noise).		
16.4.	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.		
17.	Devices connected to or equipped with an energy source		
	For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall		
17.1.	be adopted to eliminate or reduce as far as possible consequent risks.		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
17.2.	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining		
	the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes		
	critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.		
	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating		
	electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.		
	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro magnetic		
	interference such that is adequate to enable them to operate as intended.		
17.4.(1)	Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units		
	of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).		
17.5.	Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks		
	to the user, or other person both during normal use of the device and in the event of a single fault condition in the device,		
10	provided the device is installed and maintained as indicated by the manufacturer.		
	Protection against mechanical and thermal risks		
	Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.  Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses		
10.2.	inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices,		
	subject to any inspection and maintenance requirements as indicated by the manufacturer.		
	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances,		
	then appropriate protection means shall be incorporated.		
	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure		
	and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as		
	intended by the manufacturer.		
18.4.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from		
	vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations,		
	particularly at source, unless the vibrations are part of the specified performance.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless		
	the noise emitted is part of the specified performance.		
18.6.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person		
	has to handle, shall be designed and constructed in such a way as to minimise all possible risks.		
	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by		
	the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.		
N/A	The same information shall be given on moving parts and/or their housings where the direction of movement needs to be		
	known in order to avoid a risk.		
18.8.	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their		
	surroundings shall not attain potentially dangerous temperatures under normal conditions of use.		
	Protection against the risks posed by devices intended for self-testing or near-patient testing		
19.1.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform		
	appropriately for their intended purpose taking into account the skills and the means available to the intended user and the		
	influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The		
	information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in		
	order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient		
	testing, the information and the instructions provided by the manufacturer shall make clear the level of training,		
	qualifications and/or experience required by the user.		
	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to		
	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and		
19.2.(b)	reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen,		
	and also in the interpretation of the results.		
19.3.	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user		
19.3.(a)	can verify that, at the time of use, the device will perform as intended by the manufacturer; and		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
19.3.(b)	be warned if the device has failed to provide a valid result.		 _
	Performance characteristics		
9.1.	Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of		
	Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking		
	account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer		
	and in particular, where applicable		

B.T.	General Safety and Performance Requirements	A 1' 1 '1'.	Evidence of	
No.		Applicability		Compliance
9.1.(a)	the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and			
	reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range,			
	linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known			
	relevant endogenous and exogenous interference, cross- reactions; and			
9.1.(b)	the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive			
	value, likelihood ratio, expected values in normal and affected populations.			
9.2.	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the			
	manufacturer.			
9.3.	Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of			
	values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures			
	and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values			
	assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement			
	procedures.			
9.4.	The characteristics and performances of the device shall be specifically checked in the event that they may be affected when			
	the device is used for the intended use under normal conditions			
9.4.(a)	for devices for self-testing, performances obtained by laypersons;			
9.4.(b)	for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency			
	units, ambulances).			
10.	Chemical, physical and biological properties			
10.1.	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance			
	requirements referred to in Chapter I are fulfilled.			
N/A	Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical			
	incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues,			
	cells, body fluids and micro-organisms), taking account of the intended purpose of the device.			
10.2.	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and			
	residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport,			
	storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to			
	the duration and frequency of exposure.			
10.3.	Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks			
	posed by substances or particles, including wear debris, degradation products and processing residues, that may be released			
	from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction			
	('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the			
	Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable			
	serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation			
	(EC) No 1907/2006 of the European Parliament and of the Council (2).			
10.4.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional			
	ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended			
	to be used.			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
11.	Infection and microbial contamination		
11.1.	Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons. The design shall		
11.1.(a)	allow easy and safe handling;		
11.1.(b)	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary		
11.1.(c)	prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.		
11.2.	Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.		
11.3.	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.		
11.4.	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.		
11.5.	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.		
11.6.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.		
12.	Devices incorporating materials of biological origin		
N/A	Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person.		
12.(1)	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
12.(2)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration,		
N/A	Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).		
N/A	In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.		
13.	Construction of devices and interaction with their environment		
13.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
13.2.	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;		
	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;		
	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;		
	the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;		
13.2.(e)	the risks of accidental ingress of substances into the device;		
	the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended;		
	the risks of any foreseeable interference with other devices.		
13.3.	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.		
13.4.	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.		
	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.		
	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.		
	The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the en vironmental conditions in which the devices are intended to be used.		
14.	Devices with a measuring function		
	Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended purpose of the device.		
	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).		
15.	Protection against radiation		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
15.1.	Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation			
	(intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended			
	purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.			
15.2.	When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as			
	far as possible be			
15.2.(a)	designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be			
	controlled and/or adjusted; and			
15.2.(b)	fitted with visual displays and/or audible warnings of such emissions.			
15.3.	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed			
	information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of	:		
	reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and			
	performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.			
16.	Electronic programmable systems devices that incorporate electronic programmable systems and software that are devices in			
	themselves			
16.1.	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves,			
	shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single			
	fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment			
	of performance.			
16.2.	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and			
	manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk			
	management, including information security, verification and validation.			
16.3.	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be			
	designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the			
	screen) and the external factors related to their use (varying environment as regards level of light or noise).			
16.4.	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security			
10	measures, including protection against unauthorised access, necessary to run the software as intended.			
17.	Devices connected to or equipped with an energy source			
17.1.	For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall			
17.1.	be adopted to eliminate or reduce as far as possible consequent risks.			
17.2.	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining			
1,.~.	the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes			
	critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.			
	prince. If necessary, such waiting of maleuton shall be given prior to the power supply becoming critical.		Standarde	Evidence of
No.	General Safety and Performance Requirements	<b>Applicability</b>		Compliance
17.3.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating		Typhuca	Compliance
17.3.	electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the			
	intended environment.			
	pmended environment.			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
17.4.	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro magnetic interference such that is adequate to enable them to operate as intended.		
17.4.(1)	Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).		
17.5.	Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.		
18.	Protection against mechanical and thermal risks		
18.1.	Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.		
18.2.	Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.		
18.3.	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.		
N/A	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.		
18.4.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.		
18.5.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.		
18.6.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.		
18.7.	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.		
N/A	The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.		
18.8.	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.		
19.	Protection against the risks posed by devices intended for self-testing or near-patient testing		

No	Canaral Safaty and Darformance Paguirements	Applicability	Standards	Evidence of
No.	General Safety and Performance Requirements	Applicability	Applied	Compliance
19.1.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform			
	appropriately for their intended purpose taking into account the skills and the means available to the intended user and the			
	influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The			
	information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in			
	order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient			
	testing, the information and the instructions provided by the manufacturer shall make clear the level of training,			
	qualifications and/or experience required by the user.			
	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to			
` ′	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after			
	appropriate training and/or information; and			
	reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen,			
	and also in the interpretation of the results.			
19.3.	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended			
10.2 (a)	user			
	can verify that, at the time of use, the device will perform as intended by the manufacturer; and be warned if the device has failed to provide a valid result.			
_ ` ,	Performance characteristics			
	Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of			
9.1.	Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking			
	account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer			
	and in particular, where applicable			
	the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and			
5.1.(u)	reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range,			
	linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known			
	relevant endogenous and exogenous interference, cross- reactions; and			
	the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive			
	value, likelihood ratio, expected values in normal and affected populations.			
	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the			
II .	manufacturer.			
9.3.	Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of			
	values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures			
	and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values			
	assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement			
	procedures.			
	The characteristics and performances of the device shall be specifically checked in the event that they may be affected when			
	the device is used for the intended use under normal conditions			
9.4.(a)	for devices for self-testing, performances obtained by laypersons;			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
10.	Chemical, physical and biological properties		
10.1.	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled.		
N/A	Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.		
	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.		
	Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2).		
	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.		
11.	Infection and microbial contamination		
	Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons. The design shall		
	allow easy and safe handling;		
	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary		
	prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.		
	Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.		
	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
11.4.	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.		
11.5.	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices		
	are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking		
	account of the method of sterilisation indicated by the manufacturer.		
11.6.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a		
	non-sterile condition additional to the symbol used to indicate that devices are sterile.		
12.	Devices incorporating materials of biological origin		
N/A	Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the		
	processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be		
	carried out so as to provide safety for user or other person.		
12.(1)	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,		
	labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and		
	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
12.(2)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the		
	Registration,		
	Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).		
N/A	In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of		
	validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain		
	devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or		
	when such elimination or inactivation process would compromise the performance of the device.		
	Construction of devices and interaction with their environment		
13.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the		
	connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use		
	applying to such combinations shall be indicated on the label and/or in the instructions for use.		
	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible		
	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where		
	appropriate ergonomic features;		
13.2.(b)	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields,		
	external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic		
	procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;		
	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including		
	gases, to which it is exposed during normal conditions of use;		
` '	the risks associated with the possible negative interaction between software and the IT environment within which it operates		
	and interacts;		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
13.2.(e)	the risks of accidental ingress of substances into the device;		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended;		
13.2.(g)	the risks of any foreseeable interference with other devices.		
	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.		
	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.		
	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.		
13.6.	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.		
13.7	The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the en vironmental conditions in which the devices are intended to be used.		
14.	Devices with a measuring function		
	Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended purpose of the device.		
	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).		
15.	Protection against radiation		
15.1.	Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.		
	When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be		
15.2.(a)	designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and		
	fitted with visual displays and/or audible warnings of such emissions.		
	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed		
	information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of		
	reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
16.	Electronic programmable systems devices that incorporate electronic programmable systems and software that are devices in themselves		
	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.		
16.2.	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.		
	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).		
16.4.	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.		
17.	Devices connected to or equipped with an energy source		
17.1.	For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.		
17.2.	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.		
	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.		
	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro magnetic interference such that is adequate to enable them to operate as intended.		
	Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).		
	Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.		
	Protection against mechanical and thermal risks		
	Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.		
	Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.		
18.3.	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
N/A	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
18.4.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.		
18.5.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.		
18.6.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.		
18.7.	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.		
N/A	The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.		
18.8.	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.		
19.	Protection against the risks posed by devices intended for self-testing or near-patient testing		
19.1.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.		
19.2.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to		
	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and		
19.2.(b)	reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.		
	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user		
	can verify that, at the time of use, the device will perform as intended by the manufacturer; and		
_ ` /	be warned if the device has failed to provide a valid result.		
9.	Performance characteristics		

No.	General Safety and Performance Requirements	Applicability		Evidence of
110.	2	Applicability	Applied	Compliance
9.1.	Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of			
	Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking			
	account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer			
	and in particular, where applicable			
9.1.(a)	the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and			
	reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range,			
	linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known			
0.1.0.	relevant endogenous and exogenous interference, cross- reactions; and			
9.1.(b)	the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive			
0.0	value, likelihood ratio, expected values in normal and affected populations.			
9.2.	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the			
0.0	manufacturer.			
9.3.	Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of			
	values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures			
	and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values			
	assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.			
9.4.	The characteristics and performances of the device shall be specifically checked in the event that they may be affected when			
3.4.	the device is used for the intended use under normal conditions			
9.4.(a)	for devices for self-testing, performances obtained by laypersons;			
9.4.(b)	for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).			
10.	Chemical, physical and biological properties			
10.1.	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance			
10.1.	requirements referred to in Chapter I are fulfilled.			
N/A	Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical			
14/11	incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues,			
	cells, body fluids and micro-organisms), taking account of the intended purpose of the device.			
10.2.	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and			
10.2.	residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport,			
	storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to			
	the duration and frequency of exposure.			

No.	-	Applicability	Evidence of Compliance
10.3.	Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks		
	posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction		
	('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the		
	Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable		
	serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation		
	(EC) No 1907/2006 of the European Parliament and of the Council (2).		
	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional		
	ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended		
	to be used.		
	Infection and microbial contamination		
	Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the		
	risk of infection to the user or, where applicable, other persons. The design shall		
` ′	allow easy and safe handling;		
	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination		
11.1.(0)	of the specimen.		
11.2.	Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to		
	ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the		
	manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition		
	or microbial state is damaged.		
No.		Applicability	Evidence of Compliance
11.3.	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.		
	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.		
	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices		
	are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking		
	account of the method of sterilisation indicated by the manufacturer.		
11.6.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a		
12	non-sterile condition additional to the symbol used to indicate that devices are sterile.		
12. N/A	Devices incorporating materials of biological origin  Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the		
IN/A	processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be		
	carried out so as to provide safety for user or other person.		
	Latrica out 30 as to provide safety for user of other person.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
12.(1)	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,		
	labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and		
	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
12.(2)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the		
	Registration,		
	Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).		
N/A	In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of		
	validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain		
	devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or		
	when such elimination or inactivation process would compromise the performance of the device.		
13.	Construction of devices and interaction with their environment		
13.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the		
	connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use		
	applying to such combinations shall be indicated on the label and/or in the instructions for use.		
	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible		
	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where		
	appropriate ergonomic features;		
	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields,		
	external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic		
	procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;		
` ′	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including		
	gases, to which it is exposed during normal conditions of use;		
	the risks associated with the possible negative interaction between software and the IT environment within which it operates		
	and interacts;		
	the risks of accidental ingress of substances into the device;		
13.2.(f)	the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or		
	numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to		
	perform the test or assay as intended;		
13.2.(g)	the risks of any foreseeable interference with other devices.		
	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use		
	and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or		
	use in association with flammable or explosive substances or substances which could cause combustion.		
	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely		
	and effectively.		
	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such		
	a way that the interoperability and compatibility are reliable and safe.		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
13.6.	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related		Арриси	Comphance
15.0.	waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a			
	result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.			
13.7	The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and			
	manufactured in line with ergonomic principles, taking account of the intended purpose, users and the en vironmental			
	conditions in which the devices are intended to be used.			
14.	Devices with a measuring function			
14.1.	Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide			
	appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended			
	purpose of the device.			
14.2.	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions			
1.5	of Council Directive 80/181/EEC (1).			
15.	Protection against radiation		C4 JJ-	Г-: 1
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
15.1.	Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation		Applieu	Comphance
13.1.	(intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended			
	purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.			
15.2.	When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as			
13,1	far as possible be			
15.2.(a`	designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be			
	controlled and/or adjusted; and			
15.2.(b	fitted with visual displays and/or audible warnings of such emissions.			
15.3.	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed			
	information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of			
	reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and			
	performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.			
16.	Electronic programmable systems devices that incorporate electronic programmable systems and software that are devices in			
	themselves			
16.1.	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves,			
	shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single			
	fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment			
16.2	of performance.			
16.2.	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and			
	manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk			
	management, including information security, verification and validation.			

16.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).    16.4.   Manufacturers shall set our minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.   17.   Por decirces connected to or equipped with an energy source in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.   17.2.   Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becomes critical. If necessary such warning or indication shall be given prior to the power supply becomes critical. If necessary such warning or indication shall be given prior to the power supply becomes critical. If necessary such warning or indication shall be given prior to the power supply becomes critical.   17.3.   Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro magnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.   17.4.   Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro magnetic interference such that is adequate to enable them to operate as intended.   17.   Devices s	No.		Applicability	Evidence of Compliance
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	General Safety and Performance Requirements	Applicability		Evidence of
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	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person			
	has to handle, shall be designed and constructed in such a way as to minimise all possible risks.			
	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by			
	he design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.			
	The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.			
18.8. <i>A</i>	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their			
s	surroundings shall not attain potentially dangerous temperatures under normal conditions of use.			
19. F	Protection against the risks posed by devices intended for self-testing or near-patient testing			
a iii iii o te	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient esting, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.			
19.2. I	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to			
19.2.(a) e	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after			
a	appropriate training and/or information; and			
	reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.			
	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user			
19.3.(a) c	can verify that, at the time of use, the device will perform as intended by the manufacturer; and			
	be warned if the device has failed to provide a valid result.			
· · · · ·	Performance characteristics			
	Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of			
A a	Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable			
	he analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and			
	eproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range,			
li	inearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known			
r	elevant endogenous and exogenous interference, cross- reactions; and			
` ′	he clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.			

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
9.2.	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.		FF 33	· ·
9.3.	Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.			
9.4.	The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions			
9.4.(a)	for devices for self-testing, performances obtained by laypersons;			
9.4.(b)	for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).			
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
10.	Chemical, physical and biological properties			
10.1.	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled.			
N/A	Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.			
10.2.	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.			
10.3.	Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2).			
	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.			
	Infection and microbial contamination			
11.1.	Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons. The design shall			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	allow easy and safe handling;		
	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary		
` ′	prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.		
	Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.		
	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.		
11.4.	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.		
	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.		
11.6.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a		
	non-sterile condition additional to the symbol used to indicate that devices are sterile.		
12.	Devices incorporating materials of biological origin		
N/A	Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person.		
	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
12.(2)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration,		
	Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).		
N/A	In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.		
	Construction of devices and interaction with their environment		
13.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.		
	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible		
	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
13.2.(b)	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields,		 •
, ,	external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic		
	procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;		
13.2.(c)	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including		
	gases, to which it is exposed during normal conditions of use;		
13.2.(d)	the risks associated with the possible negative interaction between software and the IT environment within which it operates		
	and interacts;		
13.2.(e)	the risks of accidental ingress of substances into the device;		
13.2.(f)	the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or		
	numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to		
	perform the test or assay as intended;		
13.2.(g)	the risks of any foreseeable interference with other devices.		
	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use		
	and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or		
	use in association with flammable or explosive substances or substances which could cause combustion.		
13.4.	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely		
	and effectively.		
13.5.	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such		
	a way that the interoperability and compatibility are reliable and safe.		
13.6.	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related		
	waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a		
	result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.		
13.7	The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and		
	manufactured in line with ergonomic principles, taking account of the intended purpose, users and the en vironmental		
	conditions in which the devices are intended to be used.		
14.	Devices with a measuring function		
14.1.	Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide		
	appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended		
	purpose of the device.		
14.2.	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions		
	of Council Directive 80/181/EEC (1).		
15.	Protection against radiation		
15.1.	Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation		
	(intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended		
	purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.		
15.2.	When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as		
	far as possible be		

No.	General Safety and Performance Requirements	Applicability	Standards	Evidence of
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15.2.(a)	designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be			
	controlled and/or adjusted; and			
15.2.(b)	fitted with visual displays and/or audible warnings of such emissions.			
15.3.	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed			
	information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of			
	reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and			
	performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.			
16.	Electronic programmable systems devices that incorporate electronic programmable systems and software that are devices in			
	themselves			
16.1.	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves,			
	shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single			
	fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment			
	of performance.			
16.2.	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and			
	manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk			
	management, including information security, verification and validation.			
16.3.	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be			
	designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the			
	screen) and the external factors related to their use (varying environment as regards level of light or noise).			
16.4.	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security			
	measures, including protection against unauthorised access, necessary to run the software as intended.			
17.	Devices connected to or equipped with an energy source			
17.1.	For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall			
	be adopted to eliminate or reduce as far as possible consequent risks.			
17.2.	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining			
	the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes			
	critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.			
17.3.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating			
	electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the			
	intended environment.			
17.4.	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro magnetic			
	interference such that is adequate to enable them to operate as intended.			
17.4.(1)	Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units			
	of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).			
17.5.	Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks			
	to the user, or other person both during normal use of the device and in the event of a single fault condition in the device,			
	provided the device is installed and maintained as indicated by the manufacturer.			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
18.	Protection against mechanical and thermal risks		
18.1.	Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.		
18.2.	Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.		
18.3.	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.		
N/A	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.		
18.4.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.		
18.5.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.		
18.6.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.		
18.7.	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.		
N/A	The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.		
18.8.	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.		
19.	Protection against the risks posed by devices intended for self-testing or near-patient testing		
19.1.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.		
19.2.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to		
. ,	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and		
19.2.(b)	reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
19.3.	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user		
19.3.(a)	can verify that, at the time of use, the device will perform as intended by the manufacturer; and		
19.3.(b)	be warned if the device has failed to provide a valid result.		
	CHAPTER III REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DI	EVICE	
20.	Label and instructions for use		
20.1.	General requirements regarding the information supplied by the manufacturer		
	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available		
20.1.(a)	and kept up to date on the website, taking into account the following  The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.		
	The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.		
	Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes.		
	Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.		
	Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.		
20.1.(f)	When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.		
20.1.(g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.		
	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
	In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of			
	the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and			
	labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient space to put all the			
	information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other			
	information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.			
	The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information, as			
	appropriate, is already made available in the instructions for use.			
	Information on the label			
-	The label shall bear all of the following particulars			
	the name or trade name of the device;			
` ′	the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of			
	the device;			
20.2.(c)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of			
	business;			
	if the manufacturer has its registered place of business outside the Union, the name of its authorised rep resentative and the			
	address of the registered place of business of the authorised representative;			
, ,	an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an			
	indication of that fact;			
	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an			
	equivalent symbol, as appropriate;			
	the UDI carrier as referred to in Article 24 and Part C of Annex VI;			
	an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at			
	least in terms of year and month and, where relevant, the day, in that order;			
` '	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;			
	where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or			
	any combination of thereof, or other terms which accurately reflect the contents of the package;			
	an indication of any special storage and/or handling condition that applies;			
	where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any			
	special microbial state or state of cleanliness:			
No		Applicability	Standards Applied	Evidence of Compliance
20.2.(m)				
	any other person. This information may be kept to a minimum in which case more detailed information shall appear in			
	the instructions for use, taking into account the intended users;			
20.2.(n)				
	their accessibility (or availability), and where applicable the website address where they can be consulted;			

consistent across the Union;  20.2.(q) if the device is intended for self-testi  20.2.(r) where rapid assays are not intended for self-testi  20.2.(s) where device kits include individual devices shall comply with the labelling Regulation;  20.2.(t) the devices and separate components action to detect any potential risk possible appropriate, the information shall be 20.2.(u) the label for devices for self-testing self	e, an indication of that fact. A manufacturer's indication of single use shall be ng or near-patient testing, an indication of that fact; for self-testing or near-patient testing, the explicit exclusion hereof; reagents and articles that are made available as separate devices, each of those ng requirements contained in this Section and with the requirements of this shall be identified, where applicable in terms of batches, to allow all appropriate sed by the devices and detachable components. As far as practicable and set out on the device itself and/or, where appropriate, on the sales packaging; shall bear the following particulars erform the test (e.g. blood, urine or saliva); the test to function properly;		
consistent across the Union;  20.2.(q) if the device is intended for self-testi  20.2.(r) where rapid assays are not intended for self-testi  20.2.(s) where device kits include individual devices shall comply with the labelling Regulation;  20.2.(t) the devices and separate components action to detect any potential risk post appropriate, the information shall be 20.2.(u) the label for devices for self-testing self-tes	ing or near-patient testing, an indication of that fact; for self-testing or near-patient testing, the explicit exclusion hereof; reagents and articles that are made available as separate devices, each of those and requirements contained in this Section and with the requirements of this shall be identified, where applicable in terms of batches, to allow all appropriate sed by the devices and detachable components. As far as practicable and set out on the device itself and/or, where appropriate, on the sales packaging; shall bear the following particulars erform the test (e.g. blood, urine or saliva); the test to function properly;		
20.2.(q) if the device is intended for self-testice 20.2.(r) where rapid assays are not intended for 20.2.(s) where device kits include individual devices shall comply with the labelling Regulation;  20.2.(t) the devices and separate components action to detect any potential risk possappropriate, the information shall be 20.2.(u) the label for devices for self-testing self-testin	For self-testing or near-patient testing, the explicit exclusion hereof; reagents and articles that are made available as separate devices, each of those and requirements contained in this Section and with the requirements of this shall be identified, where applicable in terms of batches, to allow all appropriate sed by the devices and detachable components. As far as practicable and set out on the device itself and/or, where appropriate, on the sales packaging; shall bear the following particulars erform the test (e.g. blood, urine or saliva); the test to function properly;		
20.2.(r) where rapid assays are not intended for 20.2.(s) where device kits include individual devices shall comply with the labelling Regulation; 20.2.(t) the devices and separate components action to detect any potential risk possappropriate, the information shall be 20.2.(u) the label for devices for self-testing	For self-testing or near-patient testing, the explicit exclusion hereof; reagents and articles that are made available as separate devices, each of those and requirements contained in this Section and with the requirements of this shall be identified, where applicable in terms of batches, to allow all appropriate sed by the devices and detachable components. As far as practicable and set out on the device itself and/or, where appropriate, on the sales packaging; shall bear the following particulars erform the test (e.g. blood, urine or saliva); the test to function properly;		
20.2.(s) where device kits include individual devices shall comply with the labelling Regulation;  20.2.(t) the devices and separate components action to detect any potential risk post appropriate, the information shall be 20.2.(u) the label for devices for self-testing self-te	reagents and articles that are made available as separate devices, each of those ing requirements contained in this Section and with the requirements of this shall be identified, where applicable in terms of batches, to allow all appropriate sed by the devices and detachable components. As far as practicable and set out on the device itself and/or, where appropriate, on the sales packaging; shall bear the following particulars erform the test (e.g. blood, urine or saliva); the test to function properly;		
devices shall comply with the labelling Regulation;  20.2.(t) the devices and separate components action to detect any potential risk posappropriate, the information shall be 20.2.(u) the label for devices for self-testing sel	shall be identified, where applicable in terms of batches, to allow all appropriate sed by the devices and detachable components. As far as practicable and set out on the device itself and/or, where appropriate, on the sales packaging; shall bear the following particulars erform the test (e.g. blood, urine or saliva); the test to function properly;		
action to detect any potential risk pos appropriate, the information shall be 20.2.(u) the label for devices for self-testing s 20.2.(u).(i) the type of specimen(s) required to p	sed by the devices and detachable components. As far as practicable and set out on the device itself and/or, where appropriate, on the sales packaging; shall bear the following particulars erform the test (e.g. blood, urine or saliva); the test to function properly;		
appropriate, the information shall be 20.2.(u) the label for devices for self-testing s 20.2.(u).(i) the type of specimen(s) required to p	set out on the device itself and/or, where appropriate, on the sales packaging; chall bear the following particulars erform the test (e.g. blood, urine or saliva); the test to function properly;		
20.2.(u) the label for devices for self-testing s 20.2.(u).(i) the type of specimen(s) required to p	hall bear the following particulars erform the test (e.g. blood, urine or saliva); the test to function properly;		
20.2.(u).(i) the type of specimen(s) required to p	erform the test (e.g. blood, urine or saliva); the test to function properly;		
	the test to function properly;		[
	1 1 0		
20.2.(u).(ii) the need for additional materials for			
20.2.(u).(iii) contact details for further advice and	assistance.		
N/A The name of devices for self-testing	shall not reflect an intended purpose other than that specified by the manufacturer.	,	
20.3. Information on the packaging which	maintains the sterile condition of a device ('sterile packaging')		
N/A The following particulars shall appear	r on the sterile packaging		
20.3.(a) an indication permitting the sterile pa	nckaging to be recognised as such,		
20.3.(b) a declaration that the device is in a st	erile condition,		
20.3.(c) the method of sterilisation,			
20.3.(d) the name and address of the manufac	turer,		
20.3.(e) a description of the device,			
20.3.(f) the month and year of manufacture,			
an unambiguous indication of the time and, where relevant, the day, in that of	ne limit for using the device safely, expressed at least in terms of year and month order.		
	ns for use for what to do if the sterile packaging is damaged or unintentionally		
opened before use.			
20.4. Information in the instructions for us	e		
20.4.1. The instructions for use shall contain	all of the following particulars		
20.4.1.(a) the name or trade name of the device			
20.4.1.(b) the details strictly necessary for the u	ser to uniquely identify the device;		
20.4.1.(c) the device's intended purpose			
20.4.1.(c).(i) what is detected and/or measured;			
	ng, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);		
20.4.1.(c).(iii)the specific information that is intended			
N/A a physiological or pathological state;	1		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
N/A	congenital physical or mental impairments;		
N/A	the predisposition to a medical condition or a disease;		
N/A	the determination of the safety and compatibility with potential recipients;		
N/A	the prediction of treatment response or reactions;		
N/A	the definition or monitoring of therapeutic measures;		
20.4.1.(iv)	whether it is automated or not;		
20.4.1.(v)	whether it is qualitative, semi-quantitative or quantitative;		
20.4.1.(vi)	the type of specimen(s) required;		
20.4.1.(vii)	where applicable, the testing population; and		
20.4.1.(viii)	for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.		
20.4.1.(d)	an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.1.(e)	the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);		_
20.4.1.(f)	the test principle;		
20.4.1.(g)	a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);		
20.4.1.(h)	a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;		
20.4.1.(i)	a list of materials provided and a list of special materials required but not provided;		
20.4.1.(j)	for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment		
N/A	information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or		
N/A	information on any known restrictions to combinations of devices and equipment.		
20.4.1.(k)	an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;		
20.4.1.(l)	in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;		
20.4.1.(m)	if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;		
20.4.1.(n)	information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate		

No.		Applicability	Evidence of Compliance
, , , ,	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as		
	suggested by changes in its appearance that may affect performance,		
` ' ` '	warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external		
	influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects,		
	electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or		
20.44()(''')	temperature,		
, , , ,	warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably		
	foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,		
	precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine		
` ' ` '	disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,		
	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be		
20.4.1.(11).(٧)	consistent across the Union,		
20.4.1 (n) (vi)	if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection,		
	decontamination, packaging and, where appropriate, the validated method of re-sterili sation. Information shall be		
	provided to identify when the device should no longer be reused, such as signs of material degradation or the		
	maximum number of allowable reuses;		
20.4.1.(o)	any warnings and/or precautions related to potentially infectious material that is included in the device;		
	where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on		
(4)	radiation safety, or particular qualifications of the intended user;		
20.4.1.(q)	conditions for collection, handling, and preparation of the specimen;		
20.4.1.(r)	details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final		
	assembly, calibration, etc., for the device to be used as intended by the manufacturer;		
20.4.1.(s)	the information needed to verify whether the device is properly installed and is ready to perform safely and as		
	intended by the manufacturer, together with, where relevant		
N/A	details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;		
N/A	identification of any consumable components and how to replace them;		
N/A	information on any necessary calibration to ensure that the device operates properly and safely during its intended		
	lifetime;		
N/A	methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.		
20.4.1.(t)	where applicable, recommendations for quality control procedures;		
20.4.1.(u)	the metrological traceability of values assigned to calibrators and control materials, including identification of applied		
	reference materials and/or reference measurement procedures of higher order and information regarding maximum		
	(self-allowed) batch to batch variation provided with relevant figures and units of measure;		
20.4.1.(v)	assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing		
	shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to		
	batch variation provided with relevant figures and units of measure;		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
	analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;		- Transition	,
20.4.1.(x)	clinical performance characteristics as defined in Section 9.1 of this Annex;			
	the mathematical approach upon which the calculation of the analytical result is made;			
20.4.1.(z)	where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;			
20.4.1.(aa)	where relevant, reference intervals in normal and affected populations;			
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.4.1.(ab)	information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;			
20.4.1.(ac)	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate			
20.4.1.(ac).(i)	infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;			
20.4.1.(ac).(ii)	environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);			
20.4.1.(ac).(iii	physical hazards such as explosion.			
20.4.1.(ad)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;			
20.4.1.(ae)	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;			
20.4.1.(af)	a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established;			
20.4.1.(ag)	where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation;			
20.4.1.(ah)	for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.			
20.4.2.	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles			
20.4.2.(a)	details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.2.(b)	specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to		
	enable the user to use the device and to understand the result(s) produced by the device;		
20.4.2.(c)	the device's intended purpose shall provide sufficient information to enable the user to understand the medical context		
	and to allow the intended user to make a correct interpretation of the results;		
20.4.2.(d)	the results shall be expressed and presented in a way that is readily understood by the intended user;		
20.4.2.(e)	information shall be provided with advice to the user on action to be taken (in case of positive, negative or		
	indeterminate result), on the test limitations and on the possibility of false positive or false negative result.		
	Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation,		
	infection, exercise, fasting, diet or medication;		
20.4.2.(f)	the information provided shall include a statement clearly directing that the user should not take any decision of		
	medical relevance without first consulting the appropriate healthcare professional, information on disease effects and		
	prevalence, and, where available, information specific to the Member State(s) where the device is placed on the		
	market on where a user can obtain further advice such as national helplines, websites;		
20.4.2.(g)	for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition,		
	the information shall specify that the patient should only adapt the treatment if he has received the appropriate		
	training to do so.		
20.	Label and instructions for use		
20.1.	General requirements regarding the information supplied by the manufacturer		
N/A	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any		
	safety and performance information relevant to the user or any other person, as appropriate. Such information may		
	appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a		
	website, be made available and kept up to date on the website, taking into account the following		
20.1.(a)	The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the		
	particular device, its intended purpose and the technical knowledge, experience, education or training of the intended		
	user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where		
	appropriate, supplemented with drawings and diagrams.		
20.1.(b)	The information required on the label shall be provided on the device itself. If this is not practicable or appropriate,		
	some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is		
	not practicable, the information shall be set out on the packaging of multiple devices.		
20.1.(c)	Labels shall be provided in a human-readable format and may be supplemented by machine-readable information,		
	such as radio-frequency identification or bar codes.		
20.1.(d)	Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases		
	instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the		
	manufacturer without any such instructions for use.		
20.1.(e)	Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to		
	a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser		
	who in any case may request further copies to be provided free of charge.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.1.(f)	When the device is intended for professional use only, instructions for use may be provided to the user in non-paper		
	format (e.g. electronic), except when the device is intended for near-patient testing.		
20.1.(g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations,		
	contra-indications, precautions or warnings in the information supplied by the manufacturer.		
20.1.(h)	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised		
	symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the		
	harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall		
	be described in the documentation supplied with the device.		
20.1.(i)	In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking		
	account of the nature and quantity of its constituents and the form under which they are present, relevant hazard		
	pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient		
	space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the		
20.1 (;)	label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.		
20.1.(j)	The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information, as appropriate, is already made available in the instructions for use.		
20.2.	Information on the label		
N/A	The label shall bear all of the following particulars		
	the name or trade name of the device;		
20.2.(a) 20.2.(b)	the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended		
20.2.(0)	purpose of the device;		
20.2 (a)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of		
20.2.(c)	business;		
20.2.(d)	if the manufacturer has its registered place of business outside the Union, the name of its authorised rep resentative		
	and the address of the registered place of business of the authorised representative;		
20.2.(e)	an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;		
20.2.(f)	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an		
	equivalent symbol, as appropriate;		
20.2.(g)	the UDI carrier as referred to in Article 24 and Part C of Annex VI;		
20.2.(h)	an unambiguous indication of the time limit for using the device safely, without degradation of performance,		
	expressed at least in terms of year and month and, where relevant, the day, in that order;		
20.2.(i)	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of		 
	manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;		
20.2.(j)	where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical		
	count, or any combination of thereof, or other terms which accurately reflect the contents of the package;		
20.2.(k)	an indication of any special storage and/or handling condition that applies;		

No.	General Safety and Performance Requirements	Applicability		<b>Evidence of</b>
140.	2	Applicability	Applied	Compliance
20.2.(l)	where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement			
	indicating any special microbial state or state of cleanliness;			
20.2.(m)	warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to			
	any other person. This information may be kept to a minimum in which case more detailed information shall appear			
	in the instructions for use, taking into account the intended users;			
20.2.(n)	if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to			
20.2 ( )	their accessibility (or availability), and where applicable the website address where they can be consulted;			
20.2.(o)	where applicable, any particular operating instructions;			
20.2.(p)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;			
20.2.(q)	if the device is intended for self-testing or near-patient testing, an indication of that fact;			
20.2.(r)	where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;			
20.2.(s)	where device kits include individual reagents and articles that are made available as separate devices, each of those			
	devices shall comply with the labelling requirements contained in this Section and with the requirements of this			
	Regulation;			
20.2.(t)	the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate			
	action to detect any potential risk posed by the devices and detachable components. As far as practicable and			
	appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;			
20.2.(u)	the label for devices for self-testing shall bear the following particulars			
20.2.(u).(i)	the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);			
20.2.(u).(ii)	the need for additional materials for the test to function properly;			
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.2.(u).(iii)	contact details for further advice and assistance.			
N/A	The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.			
20.3.	Information on the packaging which maintains the sterile condition of a device ('sterile packaging')			
N/A	The following particulars shall appear on the sterile packaging			
20.3.(a)	an indication permitting the sterile packaging to be recognised as such,			
20.3.(b)	a declaration that the device is in a sterile condition,			
20.3.(c)	the method of sterilisation,			
20.3.(d)	the name and address of the manufacturer,			
20.3.(e)	a description of the device,			
20.3.(f)	the month and year of manufacture,			
20.3.(g)	an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month			
	and, where relevant, the day, in that order,			
20.3.(h)	an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally			
	opened before use.			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.	Information in the instructions for use		
20.4.1.	The instructions for use shall contain all of the following particulars		
20.4.1.(a)	the name or trade name of the device;		
20.4.1.(b)	the details strictly necessary for the user to uniquely identify the device;		
20.4.1.(c)	the device's intended purpose		
20.4.1.(c).(i)	what is detected and/or measured;		
20.4.1.(c).(ii)	its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);		
20.4.1.(c).(iii)	the specific information that is intended to be provided in the context of		
N/A	a physiological or pathological state;		
N/A	congenital physical or mental impairments;		
N/A	the predisposition to a medical condition or a disease;		
N/A	the determination of the safety and compatibility with potential recipients;		
N/A	the prediction of treatment response or reactions;		
N/A	the definition or monitoring of therapeutic measures;		
20.4.1.(iv)	whether it is automated or not;		
20.4.1.(v)	whether it is qualitative, semi-quantitative or quantitative;		
20.4.1.(vi)	the type of specimen(s) required;		
20.4.1.(vii)	where applicable, the testing population; and		
20.4.1.(viii)	for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for		
	which it is a companion test.		
20.4.1.(d)	an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;		
20.4.1.(e)	the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);		
20.4.1.(f)	the test principle;		
20.4.1.(g)	a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);		
20.4.1.(h)	a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;		
20.4.1.(i)	a list of materials provided and a list of special materials required but not provided;		
20.4.1.(j)	for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment		
N/A	information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or		
N/A	information on any known restrictions to combinations of devices and equipment.		

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No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.4.1.(k)	an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;		Applica	Compnance
	in-use stability which may include the storage conditions, and shelf life following the first opening of the primary			
	container, together with the storage conditions and stability of working solutions, where this is relevant;			
20.4.1.(m)	if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event			
	of the sterile packaging being damaged before use;			
20.4.1.(n)	information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of			
` '	use regarding the device. That information shall cover, where appropriate			
20.4.1.(n).(i)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as			
	suggested by changes in its appearance that may affect performance,			
20.4.1.(n).(ii)	warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external			
	influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects,			
	electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or			
	temperature,			
	warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably			
	foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other			
	procedures such as electromagnetic interference emitted by the device affecting other equipment,			
` ' ' '	precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine			
	disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,			
20.4.1.(n).(v)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be			
	consistent across the Union,			
20.4.1.(n).(vi)	if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection,			
	decontamination, packaging and, where appropriate, the validated method of re-sterili sation. Information shall be			
	provided to identify when the device should no longer be reused, such as signs of material degradation or the			
	maximum number of allowable reuses;			
20.4.1.(o)	any warnings and/or precautions related to potentially infectious material that is included in the device;			
No.	General Safety and Performance Requirements	Applicability		Evidence of
			Applied	Compliance
20.4.1.(p)	where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on			
	radiation safety, or particular qualifications of the intended user;			
20.4.1.(q)	conditions for collection, handling, and preparation of the specimen;			
20.4.1.(r)	details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final			
	assembly, calibration, etc., for the device to be used as intended by the manufacturer;			
20.4.1.(s)	the information needed to verify whether the device is properly installed and is ready to perform safely and as			
	intended by the manufacturer, together with, where relevant			
N/A	details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;			
N/A	identification of any consumable components and how to replace them;			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
N/A	information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;		
N/A	methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.		
20.4.1.(t)	where applicable, recommendations for quality control procedures;		
20.4.1.(u)	the metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;		
20.4.1.(v)	assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant figures and units of measure;		
20.4.1.(w)	analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;		
20.4.1.(x)	clinical performance characteristics as defined in Section 9.1 of this Annex;		
20.4.1.(y)	the mathematical approach upon which the calculation of the analytical result is made;		
20.4.1.(z)	where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;		
20.4.1.(aa)	where relevant, reference intervals in normal and affected populations;		
20.4.1.(ab)	information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;		
20.4.1.(ac)	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate		
` ' ` '	infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;		
20.4.1.(ac).(ii)	environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);		
20.4.1.(ac).(iii)	physical hazards such as explosion.		
	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;		
	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;		
20.4.1.(af)	a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established;		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.1.(ag)	where device kits include individual reagents and articles that may be made available as separate devices, each of		
	these devices shall comply with the instructions for use requirements contained in this Section and with the		
	requirements of this Regulation;		
20.4.1.(ah)	for devices that incorporate electronic programmable systems, including software, or software that are devices in		
	themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures,		
	including protection against unauthorised access, necessary to run the software as intended.		
20.4.2.	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles		
20.4.2.(a)	details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation		
	and information on how to run the test and interpret the results;		
20.4.2.(b)	specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;		
20.4.2.(c)	the device's intended purpose shall provide sufficient information to enable the user to understand the medical context		
	and to allow the intended user to make a correct interpretation of the results;		
20.4.2.(d)	the results shall be expressed and presented in a way that is readily understood by the intended user;		
20.4.2.(e)	information shall be provided with advice to the user on action to be taken (in case of positive, negative or		
	indeterminate result), on the test limitations and on the possibility of false positive or false negative result.		
	Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation,		
	infection, exercise, fasting, diet or medication;		
20.4.2.(f)	the information provided shall include a statement clearly directing that the user should not take any decision of		
	medical relevance without first consulting the appropriate healthcare professional, information on disease effects and		
	prevalence, and, where available, information specific to the Member State(s) where the device is placed on the		
	market on where a user can obtain further advice such as national helplines, websites;		
20.4.2.(g)	for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition,		
	the information shall specify that the patient should only adapt the treatment if he has received the appropriate		
	training to do so.		
20.	Label and instructions for use		
20.1.	General requirements regarding the information supplied by the manufacturer		
N/A	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any		
	safety and performance information relevant to the user or any other person, as appropriate. Such information may		
	appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a		
	website, be made available and kept up to date on the website, taking into account the following		
20.1.(a)	The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the		
	particular device, its intended purpose and the technical knowledge, experience, education or training of the intended		
	user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where		
	appropriate, supplemented with drawings and diagrams.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.1.(b)	The information required on the label shall be provided on the device itself. If this is not practicable or appropriate,		
	some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is		
	not practicable, the information shall be set out on the packaging of multiple devices.		
20.1.(c)	Labels shall be provided in a human-readable format and may be supplemented by machine-readable information,		
	such as radio-frequency identification or bar codes.		
20.1.(d)	Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases		
	instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the		
	manufacturer without any such instructions for use.		
20.1.(e)	Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to		
	a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser		
	who in any case may request further copies to be provided free of charge.		
20.1.(f)	When the device is intended for professional use only, instructions for use may be provided to the user in non-paper		
	format (e.g. electronic), except when the device is intended for near-patient testing.		
20.1.(g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations,		
	contra-indications, precautions or warnings in the information supplied by the manufacturer.		
20.1.(h)	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised		
	symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the		
	harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall		
	be described in the documentation supplied with the device.		
20.1.(i)	In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking		
	account of the nature and quantity of its constituents and the form under which they are present, relevant hazard		
	pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient		
	space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the		
	label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.		
20.1.(j)	The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information,		
	as appropriate, is already made available in the instructions for use.		
20.2.	Information on the label		
N/A	The label shall bear all of the following particulars		
20.2.(a)	the name or trade name of the device;		
20.2.(b)	the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended		
	purpose of the device;		
20.2.(c)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of		
	business;		
20.2.(d)	if the manufacturer has its registered place of business outside the Union, the name of its authorised rep resentative		
	and the address of the registered place of business of the authorised representative;		
20.2.(e)	an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance		
	study', an indication of that fact;		

No.	General Safety and Performance Requirements	Applicability		Evidence of
			Applied	Compliance
20.2.(f)	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an			
	equivalent symbol, as appropriate;			
20.2.(g)	the UDI carrier as referred to in Article 24 and Part C of Annex VI;			
20.2.(h)	an unambiguous indication of the time limit for using the device safely, without degradation of performance,			
	expressed at least in terms of year and month and, where relevant, the day, in that order;			
20.2.(i)	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of			
	manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;			
20.2.(j)	where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical			
	count, or any combination of thereof, or other terms which accurately reflect the contents of the package;			
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.2.(k)	an indication of any special storage and/or handling condition that applies;			
20.2.(l)	where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating			
	any special microbial state or state of cleanliness;			
20.2.(m)	warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to			
	any other person. This information may be kept to a minimum in which case more detailed information shall appear in			
	the instructions for use, taking into account the intended users;			
20.2.(n)	if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to			
	their accessibility (or availability), and where applicable the website address where they can be consulted;			
20.2.(o)	where applicable, any particular operating instructions;			
20.2.(p)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be			
	consistent across the Union;			
20.2.(q)	if the device is intended for self-testing or near-patient testing, an indication of that fact;			
20.2.(r)	where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;			
20.2.(s)	where device kits include individual reagents and articles that are made available as separate devices, each of those			
	devices shall comply with the labelling requirements contained in this Section and with the requirements of this			
	Regulation;			
20.2.(t)	the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate			
	action to detect any potential risk posed by the devices and detachable components. As far as practicable and			
20.2 ( )	appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;			
20.2.(u)	the label for devices for self-testing shall bear the following particulars			
20.2.(u).(i)	the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);			
20.2.(u).(ii)	the need for additional materials for the test to function properly;			
20.2.(u).(iii)	contact details for further advice and assistance.			
N/A	The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.			
20.3.	Information on the packaging which maintains the sterile condition of a device ('sterile packaging')			
N/A	The following particulars shall appear on the sterile packaging			

No.	Coneval Safety and Devfeymence Deguivements	Applicability	Standards	Evidence of
190.	General Safety and Performance Requirements	Applicability	Applied	Compliance
20.3.(a)	an indication permitting the sterile packaging to be recognised as such,			
20.3.(b)	a declaration that the device is in a sterile condition,			
20.3.(c)	the method of sterilisation,			
20.3.(d)	the name and address of the manufacturer,			
20.3.(e)	a description of the device,			
20.3.(f)	the month and year of manufacture,			
20.3.(g)	an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order,			
20.3.(h)	an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.			
20.4.	Information in the instructions for use			
20.4.1.	The instructions for use shall contain all of the following particulars			
20.4.1.(a)	the name or trade name of the device;			
20.4.1.(b)	the details strictly necessary for the user to uniquely identify the device;			
20.4.1.(c)	the device's intended purpose			
20.4.1.(c).(i)	what is detected and/or measured;			
20.4.1.(c).(ii)	its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);			
20.4.1.(c).(iii)	the specific information that is intended to be provided in the context of			
N/A	a physiological or pathological state;			
N/A	congenital physical or mental impairments;			
N/A	the predisposition to a medical condition or a disease;			
N/A	the determination of the safety and compatibility with potential recipients;			
N/A	the prediction of treatment response or reactions;			
N/A	the definition or monitoring of therapeutic measures;			
20.4.1.(iv)	whether it is automated or not;			
20.4.1.(v)	whether it is qualitative, semi-quantitative or quantitative;			
20.4.1.(vi)	the type of specimen(s) required;			
20.4.1.(vii)	where applicable, the testing population; and			
20.4.1.(viii)	for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for			
20.44(1)	which it is a companion test.			
20.4.1.(d)	an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance			
20.41(a)	study', an indication of that fact;	-		
20.4.1.(e)	the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);			
20.4.1.(f)	the test principle;			
20.4.1.(g)	a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument			
	only);			

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.4.1.(h)	a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the			
	composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s)			
	or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the			
	measurement;			
	a list of materials provided and a list of special materials required but not provided;			
٠,	for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment			
N/A	information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or			
N/A	information on any known restrictions to combinations of devices and equipment.			
20.4.1.(k)	an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;			
	in-use stability which may include the storage conditions, and shelf life following the first opening of the primary			
20.41()	container, together with the storage conditions and stability of working solutions, where this is relevant;			
, ,	if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event			
	of the sterile packaging being damaged before use;			
	information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate			
	use regarding the device. That information shall cover, where appropriate		C4 J J-	Evidence of
No.	General Safety and Performance Requirements	Applicability		<b>Compliance</b>
<b>No.</b> 20.4.1.(n).(i)	General Safety and Performance Requirements  warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as	Applicability		
	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,	Applicability		
	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external	Applicability		
20.4.1.(n).(i)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects,	Applicability		
20.4.1.(n).(i)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or	Applicability		
20.4.1.(n).(i) 20.4.1.(n).(ii)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,	Applicability		
20.4.1.(n).(i) 20.4.1.(n).(ii)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably	Applicability		
20.4.1.(n).(i) 20.4.1.(n).(ii)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or	Applicability		
20.4.1.(n).(i) 20.4.1.(n).(ii) 20.4.1.(n).(iii)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,	Applicability		
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20.4.1.(n).(ii) 20.4.1.(n).(iii) 20.4.1.(n).(iii) 20.4.1.(n).(iv)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,	Applicability		
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20.4.1.(n).(i) 20.4.1.(n).(ii) 20.4.1.(n).(iii) 20.4.1.(n).(iv) 20.4.1.(n).(v)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user, if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union, if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterili sation. Information shall be provided to identify when the device should no longer be reused, such as signs of material degradation or the	Applicability		
20.4.1.(n).(ii) 20.4.1.(n).(iii) 20.4.1.(n).(iii) 20.4.1.(n).(iv) 20.4.1.(n).(v)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user, if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union, if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterili sation. Information shall be	Applicability		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.4.1.(p)	where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on			
	radiation safety, or particular qualifications of the intended user;			
20.4.1.(q)	conditions for collection, handling, and preparation of the specimen;			
20.4.1.(r)	details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final			
	assembly, calibration, etc., for the device to be used as intended by the manufacturer;			
20.4.1.(s)	the information needed to verify whether the device is properly installed and is ready to perform safely and as			
	intended by the manufacturer, together with, where relevant			
N/A	details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;			
N/A	identification of any consumable components and how to replace them;			
N/A	information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;			
N/A	methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.			
20.4.1.(t)	where applicable, recommendations for quality control procedures;			
20.4.1.(u)	the metrological traceability of values assigned to calibrators and control materials, including identification of applied			
	reference materials and/or reference measurement procedures of higher order and information regarding maximum			
	(self-allowed) batch to batch variation provided with relevant figures and units of measure;			
20.4.1.(v)	assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing			
	shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch			
	to batch variation provided with relevant figures and units of measure;			
20.4.1.(w)	analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision			
	(repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and			
	measurement range, (information needed for the control of known relevant interferences, cross-reactions and			
	limitations of the method), measuring range, linearity and information about the use of available reference			
	measurement procedures and materials by the user;			
20.4.1.(x)	clinical performance characteristics as defined in Section 9.1 of this Annex;			
20.4.1.(y)	the mathematical approach upon which the calculation of the analytical result is made;			
20.4.1.(z)	where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic			
	specificity, positive and negative predictive value;			
20.4.1.(aa)	where relevant, reference intervals in normal and affected populations;			
20.4.1.(ab)	information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of			
	specimen) that may affect the performance of the device;			
20.4.1.(ac)	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the			
	consumables used with it, if any. This information shall cover, where appropriate			
20.4.1.(ac).(i)	infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human		<u></u>	
	origin;			
20.4.1.(ac).(ii)	environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);			
20.4.1.(ac).(iii)	physical hazards such as explosion.			

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.4.1.(ad)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of		- * *	•
, ,	business at which he can be contacted and its location be established, together with a telephone number and/or fax			
	number and/or website address to obtain technical assistance;			
20.4.1.(ae)	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision			
	of the instructions for use, with a clear indication of the introduced modifications;			
20.4.1.(af)	a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the			
	manufacturer and the competent authority of the Member State in which the user and/or the patient is established;			
20.4.1.(ag)	where device kits include individual reagents and articles that may be made available as separate devices, each of			
	these devices shall comply with the instructions for use requirements contained in this Section and with the			
	requirements of this Regulation;			
20.4.1.(ah)	for devices that incorporate electronic programmable systems, including software, or software that are devices in			
	themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures,			
	including protection against unauthorised access, necessary to run the software as intended.			
20.4.2.	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following			
	principles			
20.4.2.(a)	details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation			
	and information on how to run the test and interpret the results;			
20.4.2.(b)	specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to			
	enable the user to use the device and to understand the result(s) produced by the device;			
20.4.2.(c)	the device's intended purpose shall provide sufficient information to enable the user to understand the medical context			
	and to allow the intended user to make a correct interpretation of the results;			
20.4.2.(d)	the results shall be expressed and presented in a way that is readily understood by the intended user;			
20.4.2.(e)	information shall be provided with advice to the user on action to be taken (in case of positive, negative or			
	indeterminate result), on the test limitations and on the possibility of false positive or false negative result.			
	Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation,			
	infection, exercise, fasting, diet or medication;			
20.4.2.(f)	the information provided shall include a statement clearly directing that the user should not take any decision of			
	medical relevance without first consulting the appropriate healthcare professional, information on disease effects and			
	prevalence, and, where available, information specific to the Member State(s) where the device is placed on the			
	market on where a user can obtain further advice such as national helplines, websites;			
20.4.2.(g)	for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition,			
	the information shall specify that the patient should only adapt the treatment if he has received the appropriate			
	training to do so.			
20.	Label and instructions for use			
20.1.	General requirements regarding the information supplied by the manufacturer			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
N/A	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any		
	safety and performance information relevant to the user or any other person, as appropriate. Such information may		
	appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a		
	website, be made available and kept up to date on the website, taking into account the following		
20.1.(a)	The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the		
	particular device, its intended purpose and the technical knowledge, experience, education or training of the intended		
	user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where		
	appropriate, supplemented with drawings and diagrams.		
20.1.(b)	The information required on the label shall be provided on the device itself. If this is not practicable or appropriate,		
	some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is		
	not practicable, the information shall be set out on the packaging of multiple devices.		
20.1.(c)	Labels shall be provided in a human-readable format and may be supplemented by machine-readable information,		
	such as radio-frequency identification or bar codes.		
20.1.(d)	Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases		
	instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the		
	manufacturer without any such instructions for use.		
20.1.(e)	Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to		
	a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser		
	who in any case may request further copies to be provided free of charge.		
20.1.(f)	When the device is intended for professional use only, instructions for use may be provided to the user in non-paper		
	format (e.g. electronic), except when the device is intended for near-patient testing.		
20.1.(g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations,		
	contra-indications, precautions or warnings in the information supplied by the manufacturer.		
20.1.(h)	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised		
	symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the		
	harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall		
	be described in the documentation supplied with the device.		
20.1.(i)	In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking		
	account of the nature and quantity of its constituents and the form under which they are present, relevant hazard		
	pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient		
	space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the		
	label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.		
20.1.(j)	The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information,		
	as appropriate, is already made available in the instructions for use.		
20.2.	Information on the label		
N/A	The label shall bear all of the following particulars		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.2.(a)	the name or trade name of the device;		търрисс	Сотристе
20.2.(b)	the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;			
20.2.(c)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;			
20.2.(d)	if the manufacturer has its registered place of business outside the Union, the name of its authorised rep resentative and the address of the registered place of business of the authorised representative;			
20.2.(e)	an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;			
20.2.(f)	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;			
20.2.(g)	the UDI carrier as referred to in Article 24 and Part C of Annex VI;			
20.2.(h)	an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;			
20.2.(i)	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;			
20.2.(j)	where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;			
20.2.(k)	an indication of any special storage and/or handling condition that applies;			
20.2.(1)	where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;			
20.2.(m)	warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;			
20.2.(n)	if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their accessibility (or availability), and where applicable the website address where they can be consulted;			
20.2.(o)	where applicable, any particular operating instructions;			
20.2.(p)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;			
20.2.(q)	if the device is intended for self-testing or near-patient testing, an indication of that fact;			
20.2.(r)	where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;			
20.2.(s)	where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;			
20.2.(t)	the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. As far as practicable and appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;			

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.2.(u)	the label for devices for self-testing shall bear the following particulars		rr	<b>P</b> 2 22
20.2.(u).(i)	the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);			
20.2.(u).(ii)	the need for additional materials for the test to function properly;			
20.2.(u).(iii)	contact details for further advice and assistance.			
N/A	The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.			
20.3.	Information on the packaging which maintains the sterile condition of a device ('sterile packaging')			
N/A	The following particulars shall appear on the sterile packaging			
20.3.(a)	an indication permitting the sterile packaging to be recognised as such,			
20.3.(b)	a declaration that the device is in a sterile condition,			
20.3.(c)	the method of sterilisation,			
20.3.(d)	the name and address of the manufacturer,			
20.3.(e)	a description of the device,			
20.3.(f)	the month and year of manufacture,			
20.3.(g)	an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month			
	and, where relevant, the day, in that order,			
20.3.(h)	an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally			
	opened before use.			
20.4.	Information in the instructions for use			
20.4.1.	The instructions for use shall contain all of the following particulars			
20.4.1.(a)	the name or trade name of the device;			
20.4.1.(b)	the details strictly necessary for the user to uniquely identify the device;			
20.4.1.(c)	the device's intended purpose			
20.4.1.(c).(i)	what is detected and/or measured;			
20.4.1.(c).(ii)	its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);			
20.4.1.(c).(iii)	the specific information that is intended to be provided in the context of			
N/A	a physiological or pathological state;			
N/A	congenital physical or mental impairments;			
N/A	the predisposition to a medical condition or a disease;			
N/A	the determination of the safety and compatibility with potential recipients;			
N/A	the prediction of treatment response or reactions;			
N/A	the definition or monitoring of therapeutic measures;			
20.4.1.(iv)	whether it is automated or not;			
20.4.1.(v)	whether it is qualitative, semi-quantitative or quantitative;			
20.4.1.(vi)	the type of specimen(s) required;			
20.4.1.(vii)	where applicable, the testing population; and			

No.	General Safety and Performance Requirements	Applicability		Evidence of
20.41(-:::)			Applied	Compliance
20.4.1.(viii)	for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.			
20.4.1.(d)	an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance			
20.4.1.(u)	study', an indication of that fact;			
20.4.1.(e)	the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);			
20.4.1.(f)	the test principle;			
20.4.1.(g)	a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);			
20.4.1.(h)	a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;			
20.4.1.(i)	a list of materials provided and a list of special materials required but not provided;			
20.4.1.(j)	for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment			
N/A	information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or			
N/A	information on any known restrictions to combinations of devices and equipment.			
20.4.1.(k)	an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;			
20.4.1.(l)	in-use stability which may include the storage conditions, and shelf life following the first opening of the primary			
	container, together with the storage conditions and stability of working solutions, where this is relevant;			
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.4.1.(m)	if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;			
20.4.1.(n)	information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate			
20.4.1.(n).(i)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,			
20.4.1.(n).(ii)	warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,			
20.4.1.(n).(iii)	warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,			

No.	Conoral Safety and Derformance Peguirements	Applicability	Standards	Evidence of
INU.	General Safety and Performance Requirements	Applicability	Applied	Compliance
` ' ' '	precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine			
	disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,			
` , ` ,	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be			
	consistent across the Union,			
	if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection,			
	decontamination, packaging and, where appropriate, the validated method of re-sterili sation. Information shall be			
	provided to identify when the device should no longer be reused, such as signs of material degradation or the			
	maximum number of allowable reuses;			
	any warnings and/or precautions related to potentially infectious material that is included in the device;			
· · ·	where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on			
	radiation safety, or particular qualifications of the intended user;			
	conditions for collection, handling, and preparation of the specimen;			
	details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final			
	assembly, calibration, etc., for the device to be used as intended by the manufacturer;			
	the information needed to verify whether the device is properly installed and is ready to perform safely and as			
	intended by the manufacturer, together with, where relevant			
	details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;			
	identification of any consumable components and how to replace them;			
N/A	information on any necessary calibration to ensure that the device operates properly and safely during its intended			
	lifetime;			
	methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.			
	where applicable, recommendations for quality control procedures;			
` '	the metrological traceability of values assigned to calibrators and control materials, including identification of applied			
	reference materials and/or reference measurement procedures of higher order and information regarding maximum			
	(self-allowed) batch to batch variation provided with relevant figures and units of measure;			
	assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing			
	shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch			
	to batch variation provided with relevant figures and units of measure;			
	analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision			
	(repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and			
	measurement range, (information needed for the control of known relevant interferences, cross-reactions and			
	limitations of the method), measuring range, linearity and information about the use of available reference			
	measurement procedures and materials by the user;			-
	clinical performance characteristics as defined in Section 9.1 of this Annex;			<u> </u>
	the mathematical approach upon which the calculation of the analytical result is made;			
` '	where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic			
	specificity, positive and negative predictive value;			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.1.(aa)	where relevant, reference intervals in normal and affected populations;		
20.4.1.(ab)	information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;		
20.4.1.(ac)	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate		
20.4.1.(ac).(i)	infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;		
20.4.1.(ac).(ii)	environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);		
20.4.1.(ac).(iii)	physical hazards such as explosion.		
20.4.1.(ad)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;		
20.4.1.(ae)	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;		
20.4.1.(af)	a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established;		
20.4.1.(ag)	where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation;		
20.4.1.(ah)	for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.		
20.4.2.	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles		
20.4.2.(a)	details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;		
20.4.2.(b)	specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;		
20.4.2.(c)	the device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;		
20.4.2.(d)	the results shall be expressed and presented in a way that is readily understood by the intended user;		
20.4.2.(e)	information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.2.(f)	the information provided shall include a statement clearly directing that the user should not take any decision of		
	medical relevance without first consulting the appropriate healthcare professional, information on disease effects and		
	prevalence, and, where available, information specific to the Member State(s) where the device is placed on the		
	market on where a user can obtain further advice such as national helplines, websites;		
20.4.2.(g)	for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition,		
	the information shall specify that the patient should only adapt the treatment if he has received the appropriate		
	training to do so.		
20.	Label and instructions for use		
20.1.	General requirements regarding the information supplied by the manufacturer		
N/A	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any		
	safety and performance information relevant to the user or any other person, as appropriate. Such information may		
	appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a		
	website, be made available and kept up to date on the website, taking into account the following		
20.1.(a)	The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the		
	particular device, its intended purpose and the technical knowledge, experience, education or training of the intended		
	user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where		
	appropriate, supplemented with drawings and diagrams.		
20.1.(b)	The information required on the label shall be provided on the device itself. If this is not practicable or appropriate,		
	some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is		
	not practicable, the information shall be set out on the packaging of multiple devices.		
20.1.(c)	Labels shall be provided in a human-readable format and may be supplemented by machine-readable information,		
	such as radio-frequency identification or bar codes.		
20.1.(d)	Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases		
	instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the		
	manufacturer without any such instructions for use.		
20.1.(e)	Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to		
	a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser		
	who in any case may request further copies to be provided free of charge.		
20.1.(f)	When the device is intended for professional use only, instructions for use may be provided to the user in non-paper		
	format (e.g. electronic), except when the device is intended for near-patient testing.		
20.1.(g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations,		
	contra-indications, precautions or warnings in the information supplied by the manufacturer.		
20.1.(h)	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised		
	symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the		
	harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall		
	be described in the documentation supplied with the device.		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.1.(i)	In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking		
	account of the nature and quantity of its constituents and the form under which they are present, relevant hazard		
	pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient		
	space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the		
	label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.		
20.1.(j)	The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information,		
	as appropriate, is already made available in the instructions for use.		
20.2.	Information on the label		
N/A	The label shall bear all of the following particulars		
20.2.(a)	the name or trade name of the device;		
20.2.(b)	the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;		
20.2.(c)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;		
20.2.(d)	if the manufacturer has its registered place of business outside the Union, the name of its authorised rep resentative and the address of the registered place of business of the authorised representative;		
20.2.(e)	an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;		
20.2.(f)	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an		
20.2 ( )	equivalent symbol, as appropriate;		
20.2.(g)	the UDI carrier as referred to in Article 24 and Part C of Annex VI;		
20.2.(h)	an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;		
20.2.(i)	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;		
20.2.(j)	where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;		
20.2.(k)	an indication of any special storage and/or handling condition that applies;		
20.2.(1)	where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement		
	indicating any special microbial state or state of cleanliness;		
20.2.(m)	warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to		
	any other person. This information may be kept to a minimum in which case more detailed information shall appear		
	in the instructions for use, taking into account the intended users;		
20.2.(n)	if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to		
\ \ \	their accessibility (or availability), and where applicable the website address where they can be consulted;		
20.2.(o)	where applicable, any particular operating instructions;		

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.2.(p)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be		 •
	consistent across the Union;		
20.2.(q)	if the device is intended for self-testing or near-patient testing, an indication of that fact;		
20.2.(r)	where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;		
20.2.(s)	where device kits include individual reagents and articles that are made available as separate devices, each of those		
	devices shall comply with the labelling requirements contained in this Section and with the requirements of this		
	Regulation;		
20.2.(t)	the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate		
	action to detect any potential risk posed by the devices and detachable components. As far as practicable and		
	appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;		
No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
	the label for devices for self-testing shall bear the following particulars		
20.2.(u).(i)	the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);		
20.2.(u).(ii)	the need for additional materials for the test to function properly;		
20.2.(u).(iii)	contact details for further advice and assistance.		
N/A	The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.		
20.3.	Information on the packaging which maintains the sterile condition of a device ('sterile packaging')		
N/A	The following particulars shall appear on the sterile packaging		
20.3.(a)	an indication permitting the sterile packaging to be recognised as such,		
20.3.(b)	a declaration that the device is in a sterile condition,		
20.3.(c)	the method of sterilisation,		
20.3.(d)	the name and address of the manufacturer,		
20.3.(e)	a description of the device,		
20.3.(f)	the month and year of manufacture,		
20.3.(g)	an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month		
	and, where relevant, the day, in that order,		
20.3.(h)	an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally		
	opened before use.		
20.4.	Information in the instructions for use		
20.4.1.	The instructions for use shall contain all of the following particulars		
20.4.1.(a)	the name or trade name of the device;		
20.4.1.(b)	the details strictly necessary for the user to uniquely identify the device;		
	the device's intended purpose		
20.4.1.(c).(i)	what is detected and/or measured;		
20.4.1.(c).(ii)	its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);		
	the specific information that is intended to be provided in the context of		

No.		Applicability	Evidence of Compliance
N/A	a physiological or pathological state;		
N/A	congenital physical or mental impairments;		
N/A	the predisposition to a medical condition or a disease;		
N/A	the determination of the safety and compatibility with potential recipients;		
N/A	the prediction of treatment response or reactions;		
N/A	the definition or monitoring of therapeutic measures;		
20.4.1.(iv)	whether it is automated or not;		
20.4.1.(v)	whether it is qualitative, semi-quantitative or quantitative;		
20.4.1.(vi)	the type of specimen(s) required;		
20.4.1.(vii)	where applicable, the testing population; and		
20.4.1.(viii)	for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.		
20.4.1.(d)	an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;		
20.4.1.(e)	the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);		
20.4.1.(f)	the test principle;		
20.4.1.(g)	a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);		
20.4.1.(h)	a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;		
20.4.1.(i)	a list of materials provided and a list of special materials required but not provided;		
20.4.1.(j)	for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment		
N/A	information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or		
N/A	information on any known restrictions to combinations of devices and equipment.		
20.4.1.(k)	an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;		
20.4.1.(l)	in-use stability which may include the storage conditions, and shelf life following the first opening of the primary		
	container, together with the storage conditions and stability of working solutions, where this is relevant;		
20.4.1.(m)	if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;		
20.4.1.(n)	information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate		

No.		Applicability	Evidence of Compliance
, , , ,	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as		
	suggested by changes in its appearance that may affect performance,		
` ' ` '	warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external		
	influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects,		
	electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or		
20.44()(''')	temperature,		
, , , ,	warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably		
	foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,		
	precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine		
` ' ` '	disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,		
	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be		
20.4.1.(11).(٧)	consistent across the Union,		
20.4.1 (n) (vi)	if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection,		
	decontamination, packaging and, where appropriate, the validated method of re-sterili sation. Information shall be		
	provided to identify when the device should no longer be reused, such as signs of material degradation or the		
	maximum number of allowable reuses;		
20.4.1.(o)	any warnings and/or precautions related to potentially infectious material that is included in the device;		
	where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on		
47	radiation safety, or particular qualifications of the intended user;		
20.4.1.(q)	conditions for collection, handling, and preparation of the specimen;		
20.4.1.(r)	details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final		
	assembly, calibration, etc., for the device to be used as intended by the manufacturer;		
20.4.1.(s)	the information needed to verify whether the device is properly installed and is ready to perform safely and as		
	intended by the manufacturer, together with, where relevant		
N/A	details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;		
N/A	identification of any consumable components and how to replace them;		
N/A	information on any necessary calibration to ensure that the device operates properly and safely during its intended		
	lifetime;		
N/A	methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.		
20.4.1.(t)	where applicable, recommendations for quality control procedures;		
	the metrological traceability of values assigned to calibrators and control materials, including identification of applied		
	reference materials and/or reference measurement procedures of higher order and information regarding maximum		
	(self-allowed) batch to batch variation provided with relevant figures and units of measure;		
20.4.1.(v)	assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing		
	shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to		
	batch variation provided with relevant figures and units of measure;		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.4.1.(w)	analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision		11	•
, ,	(repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and			
	measurement range, (information needed for the control of known relevant interferences, cross-reactions and			
	limitations of the method), measuring range, linearity and information about the use of available reference			
	measurement procedures and materials by the user;			
	clinical performance characteristics as defined in Section 9.1 of this Annex;			
20.4.1.(y)	the mathematical approach upon which the calculation of the analytical result is made;			
20.4.1.(z)	where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic			
	specificity, positive and negative predictive value;			
20.4.1.(aa)	where relevant, reference intervals in normal and affected populations;			
	information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of			
	specimen) that may affect the performance of the device;			
No.	General Safety and Performance Requirements	<b>Applicability</b>		Evidence of
		rpplicability	Applied	Compliance
20.4.1.(ac)	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the			
	consumables used with it, if any. This information shall cover, where appropriate			
20.4.1.(ac).(i)	infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human			
	origin;			
	environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);			
	physical hazards such as explosion.			
20.4.1.(ad)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of			
	business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;			
20.4.1.(ae)	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision			
	of the instructions for use, with a clear indication of the introduced modifications;			
20.4.1.(af)	a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the			
, ,	manufacturer and the competent authority of the Member State in which the user and/or the patient is established;			
20.4.1.(ag)	where device kits include individual reagents and articles that may be made available as separate devices, each of			
	these devices shall comply with the instructions for use requirements contained in this Section and with the			
	requirements of this Regulation;			
20.4.1.(ah)	for devices that incorporate electronic programmable systems, including software, or software that are devices in			
	themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures,			
	including protection against unauthorised access, necessary to run the software as intended.			
20.4.2.	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following			
	principles			
20.4.2.(a)	details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation			
	and information on how to run the test and interpret the results;			

No.	General Safety and Performance Requirements	Applicability	1	Evidence of Compliance
20.4.2.(b)	specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;			
20.4.2.(c)	the device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;			
20.4.2.(d)	the results shall be expressed and presented in a way that is readily understood by the intended user;			
20.4.2.(e)	information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;			
20.4.2.(f)	the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice such as national helplines, websites;			
20.4.2.(g)	for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.			
20.	Label and instructions for use			
20.1.	General requirements regarding the information supplied by the manufacturer			
N/A	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following			
20.1.(a)	The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.			
20.1.(b)	The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.			
20.1.(c)	Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes.			
20.1.(d)	Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.			
20.1.(e)	Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.			

No.	General Safety and Performance Requirements	Applicability		Evidence of
	Ž Ž	Applicability	Applied	Compliance
20.1.(f)	When the device is intended for professional use only, instructions for use may be provided to the user in non-paper			
	format (e.g. electronic), except when the device is intended for near-patient testing.			
20.1.(g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations,			
	contra-indications, precautions or warnings in the information supplied by the manufacturer.			
20.1.(h)	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised			
	symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the			
	harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall			
	be described in the documentation supplied with the device.			
20.1.(i)	In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking			
	account of the nature and quantity of its constituents and the form under which they are present, relevant hazard			
	pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient			
	space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the			
20.1 (;)	label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.			
20.1.(j)	The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information,			
20.2.	as appropriate, is already made available in the instructions for use.  Information on the label			
20.2. N/A				
	The label shall bear all of the following particulars			
20.2.(a)	the name or trade name of the device; the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended			
20.2.(b)	purpose of the device;			
20.2 (a)				
20.2.(c)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;			
20.2.(d)	if the manufacturer has its registered place of business outside the Union, the name of its authorised rep resentative			
20.2.(u)	and the address of the registered place of business of the authorised representative;			
20.2.(e)	an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance			
20.2.(0)	study', an indication of that fact;			
20.2.(f)	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an			
	equivalent symbol, as appropriate;			
20.2.(g)	the UDI carrier as referred to in Article 24 and Part C of Annex VI;			
20.2.(h)	an unambiguous indication of the time limit for using the device safely, without degradation of performance,			
	expressed at least in terms of year and month and, where relevant, the day, in that order;			
20.2.(i)	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of			
	manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;			
20.2.(j)	where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical			
9/	count, or any combination of thereof, or other terms which accurately reflect the contents of the package;			
20.2.(k)	an indication of any special storage and/or handling condition that applies;			

No.	General Safety and Performance Requirements	Applicability Standards		SEvidence of	
140.		Applicability	Applied	Compliance	
20.2.(l)	where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement				
	indicating any special microbial state or state of cleanliness;				
20.2.(m)	warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to				
	any other person. This information may be kept to a minimum in which case more detailed information shall appear				
	in the instructions for use, taking into account the intended users;				
20.2.(n)	if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to				
	their accessibility (or availability), and where applicable the website address where they can be consulted;				
20.2.(o)	where applicable, any particular operating instructions;				
20.2.(p)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;				
20.2.(q)	if the device is intended for self-testing or near-patient testing, an indication of that fact;				
20.2.(r)	where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;				
20.2.(s)	where device kits include individual reagents and articles that are made available as separate devices, each of those				
	devices shall comply with the labelling requirements contained in this Section and with the requirements of this				
	Regulation;				
20.2.(t)	the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate				
, ,	action to detect any potential risk posed by the devices and detachable components. As far as practicable and				
	appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;				
20.2.(u)	the label for devices for self-testing shall bear the following particulars				
20.2.(u).(i)	the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);				
20.2.(u).(ii)	the need for additional materials for the test to function properly;				
20.2.(u).(iii)	contact details for further advice and assistance.				
N/A	The name of devices for self-testing shall not reflect an intended purpose other than that specified by the				
	manufacturer.				
20.3.	Information on the packaging which maintains the sterile condition of a device ('sterile packaging')				
N/A	The following particulars shall appear on the sterile packaging				
20.3.(a)	an indication permitting the sterile packaging to be recognised as such,				
20.3.(b)	a declaration that the device is in a sterile condition,				
20.3.(c)	the method of sterilisation,				
20.3.(d)	the name and address of the manufacturer,				
20.3.(e)	a description of the device,				
20.3.(f)	the month and year of manufacture,				
20.3.(g)	an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order,				
20.3.(h)	an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally				
	opened before use.				
20.4.	Information in the instructions for use				
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No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.4.1.	The instructions for use shall contain all of the following particulars		търршей	Сотрани
20.4.1.(a)	the name or trade name of the device;			
20.4.1.(b)	the details strictly necessary for the user to uniquely identify the device;			
20.4.1.(c)	the device's intended purpose			
20.4.1.(c).(i)	what is detected and/or measured;			
20.4.1.(c).(ii)	its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);			
	the specific information that is intended to be provided in the context of			
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
N/A	a physiological or pathological state;			•
N/A	congenital physical or mental impairments;			
N/A	the predisposition to a medical condition or a disease;			
N/A	the determination of the safety and compatibility with potential recipients;			
N/A	the prediction of treatment response or reactions;			
N/A	the definition or monitoring of therapeutic measures;			
20.4.1.(iv)	whether it is automated or not;			
20.4.1.(v)	whether it is qualitative, semi-quantitative or quantitative;			
20.4.1.(vi)	the type of specimen(s) required;			
20.4.1.(vii)	where applicable, the testing population; and			
20.4.1.(viii)	for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for			
	which it is a companion test.			
` '	an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;			
20.4.1.(e)	the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);			
20.4.1.(f)	the test principle;			
20.4.1.(g)	a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);			
20.4.1.(h)	a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s)			
	or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;			
20.4.1.(i)	a list of materials provided and a list of special materials required but not provided;			
20.4.1.(j)	for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment			
N/A	information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or			

No.	General Safety and Performance Requirements	Applicability	Standards	<b>Evidence of</b>
140.	General Safety and Performance Requirements	Applicability	Applied	Compliance
N/A	information on any known restrictions to combinations of devices and equipment.			
20.4.1.(k)	an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;			
20.4.1.(l)	in-use stability which may include the storage conditions, and shelf life following the first opening of the primary			
	container, together with the storage conditions and stability of working solutions, where this is relevant;			
20.4.1.(m)	if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event			
	of the sterile packaging being damaged before use;			
20.4.1.(n)	information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of			
	use regarding the device. That information shall cover, where appropriate			
20.4.1.(n).(i)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as			
	suggested by changes in its appearance that may affect performance,			
	warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external			
	influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects,			
	electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or			
	temperature,			
` ' ` '	warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably			
	foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or			
	other procedures such as electromagnetic interference emitted by the device affecting other equipment,			
	precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine			
	disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,			
` ' ` '	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be			
	consistent across the Union,			
	if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection,			
	decontamination, packaging and, where appropriate, the validated method of re-sterili sation. Information shall be			
	provided to identify when the device should no longer be reused, such as signs of material degradation or the			
	maximum number of allowable reuses;			
	any warnings and/or precautions related to potentially infectious material that is included in the device;			
20.4.1.(p)	where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on			
20.44()	radiation safety, or particular qualifications of the intended user;			
	conditions for collection, handling, and preparation of the specimen;			
	details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final			
	assembly, calibration, etc., for the device to be used as intended by the manufacturer;			
` '	the information needed to verify whether the device is properly installed and is ready to perform safely and as			
	intended by the manufacturer, together with, where relevant			
	details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;			
N/A	identification of any consumable components and how to replace them;			
	information on any necessary calibration to ensure that the device operates properly and safely during its intended			
	lifetime;			

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
N/A	methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.		ripplicu	Compnance
	where applicable, recommendations for quality control procedures;			
	the metrological traceability of values assigned to calibrators and control materials, including identification of applied			
	reference materials and/or reference measurement procedures of higher order and information regarding maximum			
	(self-allowed) batch to batch variation provided with relevant figures and units of measure;			
20.4.1.(v)	assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing			
	shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to			
	batch variation provided with relevant figures and units of measure;			
20.4.1.(w)	analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision			
	(repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and			
	measurement range, (information needed for the control of known relevant interferences, cross-reactions and			
	limitations of the method), measuring range, linearity and information about the use of available reference			
	measurement procedures and materials by the user;			
` ′	clinical performance characteristics as defined in Section 9.1 of this Annex;			
	the mathematical approach upon which the calculation of the analytical result is made;			
` '	where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic			
	specificity, positive and negative predictive value;			
` ′	where relevant, reference intervals in normal and affected populations;			
, ,	information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of			
	specimen) that may affect the performance of the device;			
` ′	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the			
	consumables used with it, if any. This information shall cover, where appropriate			
, , , , ,	infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human			
	origin;			
20.4.1.(ac).(ii)	environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);			
No.	General Safety and Performance Requirements	Applicability	Standards Applied	Evidence of Compliance
20.4.1.(ac).(iii)	physical hazards such as explosion.			
20.4.1.(ad)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of			
	business at which he can be contacted and its location be established, together with a telephone number and/or fax			
	number and/or website address to obtain technical assistance;			
20.4.1.(ae)	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision			
	of the instructions for use, with a clear indication of the introduced modifications;			
` '	a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the			
	manufacturer and the competent authority of the Member State in which the user and/or the patient is established;			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.1.(ag)	where device kits include individual reagents and articles that may be made available as separate devices, each of		
	these devices shall comply with the instructions for use requirements contained in this Section and with the		
	requirements of this Regulation;		
20.4.1.(ah)	for devices that incorporate electronic programmable systems, including software, or software that are devices in		
	themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures,		
	including protection against unauthorised access, necessary to run the software as intended.		
20.4.2.	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles		
20.4.2.(a)	details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation		
	and information on how to run the test and interpret the results;		
20.4.2.(b)	specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;		
20.4.2.(c)	the device's intended purpose shall provide sufficient information to enable the user to understand the medical context		
	and to allow the intended user to make a correct interpretation of the results;		
20.4.2.(d)	the results shall be expressed and presented in a way that is readily understood by the intended user;		
20.4.2.(e)	information shall be provided with advice to the user on action to be taken (in case of positive, negative or		
	indeterminate result), on the test limitations and on the possibility of false positive or false negative result.		
	Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation,		
	infection, exercise, fasting, diet or medication;		
20.4.2.(f)	the information provided shall include a statement clearly directing that the user should not take any decision of		
	medical relevance without first consulting the appropriate healthcare professional, information on disease effects and		
	prevalence, and, where available, information specific to the Member State(s) where the device is placed on the		
	market on where a user can obtain further advice such as national helplines, websites;		
20.4.2.(g)	for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition,		
	the information shall specify that the patient should only adapt the treatment if he has received the appropriate		
	training to do so.		
20.	Label and instructions for use		
20.1.	General requirements regarding the information supplied by the manufacturer		
N/A	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any		
	safety and performance information relevant to the user or any other person, as appropriate. Such information may		
	appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a		
	website, be made available and kept up to date on the website, taking into account the following		
20.1.(a)	The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the		
	particular device, its intended purpose and the technical knowledge, experience, education or training of the intended		
	user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where		
	appropriate, supplemented with drawings and diagrams.		

20.1.(b) The information required on the label shall be provided on the device itself. If this is not practic some or all of the information may appear on the packaging for each unit. If individual full laber not practicable, the information shall be set out on the packaging of multiple devices.  20.1.(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable such as radio-frequency identification or bar codes.	readable information, ceptional cases
not practicable, the information shall be set out on the packaging of multiple devices.  20.1.(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable.	radable information, ceptional cases
20.1.(c) Labels shall be provided in a human-readable format and may be supplemented by machine-rea	ceptional cases
	ceptional cases
such as radio-frequency identification or bar codes	
20.1.(d) Instructions for use shall be provided together with devices. However, in duly justified and exce	
instructions for use shall not be required or may be abbreviated if the device can be used safely	y and as intended by the
manufacturer without any such instructions for use.	
20.1.(e) Where multiple devices, with the exception of devices intended for self-testing or near-patient t	9 11
a single user and/or location, a single copy of the instructions for use may be provided if so agree	reed by the purchaser
who in any case may request further copies to be provided free of charge.	
20.1.(f) When the device is intended for professional use only, instructions for use may be provided to t	the user in non-paper
format (e.g. electronic), except when the device is intended for near-patient testing.	
20.1.(g) Residual risks which are required to be communicated to the user and/or other person shall be in	included as limitations,
contra-indications, precautions or warnings in the information supplied by the manufacturer.	
20.1.(h) Where appropriate, the information supplied by the manufacturer shall take the form of internat	ntionally recognised
symbols, taking into account the intended users. Any symbol or identification colour used shall	
harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbol	pols and colours shall
be described in the documentation supplied with the device.	
20.1.(i) In the case of devices containing a substance or a mixture which may be considered as being da	
account of the nature and quantity of its constituents and the form under which they are present	
pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where the	
space to put all the information on the device itself or on its label, the relevant hazard pictogram	<u> </u>
label and the other information required by Regulation (EC) No 1272/2008 shall be given in the	
20.1.(j) The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all	ll relevant information,
as appropriate, is already made available in the instructions for use.	
20.2. Information on the label	
N/A The label shall bear all of the following particulars	
20.2.(a) the name or trade name of the device;	
20.2.(b) the details strictly necessary for a user to identify the device and, where it is not obvious for the	e user, the intended
purpose of the device;	
20.2.(c) the name, registered trade name or registered trade mark of the manufacturer and the address of	of its registered place of
business;	
20.2.(d) if the manufacturer has its registered place of business outside the Union, the name of its author	prised rep resentative
and the address of the registered place of business of the authorised representative;	
20.2.(e) an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device	ce for performance
study', an indication of that fact;	

No.	General Safety and Performance Requirements	Applicability		Evidence of
20.2 (f)	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an		Appnea	Compliance
20.2.(f)	equivalent symbol, as appropriate;			
20.2.(g)	the UDI carrier as referred to in Article 24 and Part C of Annex VI;			
20.2.(g) 20.2.(h)	an unambiguous indication of the time limit for using the device safely, without degradation of performance,			
20.2.(11)	expressed at least in terms of year and month and, where relevant, the day, in that order;			
20.2.(i)	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of			
20.2.(1)	manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;			
20.2.(j)	where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical			
()	count, or any combination of thereof, or other terms which accurately reflect the contents of the package;			
20.2.(k)	an indication of any special storage and/or handling condition that applies;			
20.2.(l)	where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement			
	indicating any special microbial state or state of cleanliness;			
20.2.(m)	warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to			
	any other person. This information may be kept to a minimum in which case more detailed information shall appear			
	in the instructions for use, taking into account the intended users;			
20.2.(n)	if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to			
	their accessibility (or availability), and where applicable the website address where they can be consulted;			
20.2.(o)	where applicable, any particular operating instructions;			
20.2.(p)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;			
20.2.(q)	if the device is intended for self-testing or near-patient testing, an indication of that fact;			
20.2.(r)	where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;			
20.2.(s)	where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;			
20.2.(t)	the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate			
	action to detect any potential risk posed by the devices and detachable components. As far as practicable and			
	appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;			
20.2.(u)	the label for devices for self-testing shall bear the following particulars			
20.2.(u).(i)	the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);			
20.2.(u).(ii)	the need for additional materials for the test to function properly;			
20.2.(u).(iii)	contact details for further advice and assistance.			
N/A	The name of devices for self-testing shall not reflect an intended purpose other than that specified by the			
	manufacturer.			
20.3.	Information on the packaging which maintains the sterile condition of a device ('sterile packaging')			
N/A	The following particulars shall appear on the sterile packaging			
20.3.(a)	an indication permitting the sterile packaging to be recognised as such,			

No.	General Safety and Performance Requirements	Applicability		Evidence of
		рриссонсу	Applied	Compliance
20.3.(b)	a declaration that the device is in a sterile condition,			
20.3.(c)	the method of sterilisation,		C. 1 1	T . I . C
No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.3.(d)	the name and address of the manufacturer,			
20.3.(e)	a description of the device,			
20.3.(f)	the month and year of manufacture,			
20.3.(g)	an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order,			
20.3.(h)	an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.			
20.4.	Information in the instructions for use			
20.4.1.	The instructions for use shall contain all of the following particulars			
20.4.1.(a)	the name or trade name of the device;			
20.4.1.(b)	the details strictly necessary for the user to uniquely identify the device;			
	the device's intended purpose			
20.4.1.(c).(i)	what is detected and/or measured;			
20.4.1.(c).(ii)	its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);			
20.4.1.(c).(iii)	the specific information that is intended to be provided in the context of			
N/A	a physiological or pathological state;			
N/A	congenital physical or mental impairments;			
N/A	the predisposition to a medical condition or a disease;			
N/A	the determination of the safety and compatibility with potential recipients;			
N/A	the prediction of treatment response or reactions;			
N/A	the definition or monitoring of therapeutic measures;			
20.4.1.(iv)	whether it is automated or not;			
20.4.1.(v)	whether it is qualitative, semi-quantitative or quantitative;			
20.4.1.(vi)	the type of specimen(s) required;			
20.4.1.(vii)	where applicable, the testing population; and			
20.4.1.(viii)	for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for			
	which it is a companion test.			
20.4.1.(d)	an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;			
	the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);			
20.4.1.(f)	the test principle;			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.1.(g)	a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);		
20.4.1.(h)	a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;		
20.4.1.(i)	a list of materials provided and a list of special materials required but not provided;		
20.4.1.(j)	for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment		
N/A	information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or		
N/A	information on any known restrictions to combinations of devices and equipment.		
20.4.1.(k)	an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;		
20.4.1.(l)	in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;		
20.4.1.(m)	if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;		
20.4.1.(n)	information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate		
20.4.1.(n).(i)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,		
20.4.1.(n).(ii)	warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,		
20.4.1.(n).(iii	warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,		
20.4.1.(n).(iv)	precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,		
20.4.1.(n).(v)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union,		
	if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterili sation. Information shall be provided to identify when the device should no longer be reused, such as signs of material degradation or the maximum number of allowable reuses;		
20.4.1.(o)	any warnings and/or precautions related to potentially infectious material that is included in the device;		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.4.1.(p)	where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on			
	radiation safety, or particular qualifications of the intended user;			
	conditions for collection, handling, and preparation of the specimen;			
	details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final			
	assembly, calibration, etc., for the device to be used as intended by the manufacturer;			
7 7	the information needed to verify whether the device is properly installed and is ready to perform safely and as			
	intended by the manufacturer, together with, where relevant			
	details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;			
	identification of any consumable components and how to replace them;			
	information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;			
N/A	methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.			
NI.	Compared Sefects and Devicements	A li bilit	Standards	<b>Evidence of</b>
No.	General Safety and Performance Requirements	Applicability	Applied	Compliance
20.4.1.(t)	where applicable, recommendations for quality control procedures;			
20.4.1.(u)	the metrological traceability of values assigned to calibrators and control materials, including identification of applied			
	reference materials and/or reference measurement procedures of higher order and information regarding maximum			
	(self-allowed) batch to batch variation provided with relevant figures and units of measure;			
20.4.1.(v)	assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing			
	shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch			
	to batch variation provided with relevant figures and units of measure;			
20.4.1.(w)	analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and			
	measurement range, (information needed for the control of known relevant interferences, cross-reactions and			
	limitations of the method), measuring range, linearity and information about the use of available reference			
	measurement procedures and materials by the user;			
20.4.1.(x)	clinical performance characteristics as defined in Section 9.1 of this Annex;			
20.4.1.(y)	the mathematical approach upon which the calculation of the analytical result is made;			
20.4.1.(z)	where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic			
	specificity, positive and negative predictive value;			
20.4.1.(aa)	where relevant, reference intervals in normal and affected populations;			
20.4.1.(ab)	information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of			
	specimen) that may affect the performance of the device;			
20.4.1.(ac)	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the			
	consumables used with it, if any. This information shall cover, where appropriate			
20.4.1.(ac).(i)	infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human			
	origin;			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.1.(ac).(ii)	environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);		
20.4.1.(ac).(iii)	physical hazards such as explosion.		
	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;		
	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;		
` '	a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established;		
	where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation;		
	for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.		
	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles		
	details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;		
	specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;		
	the device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;		
20.4.2.(d)	the results shall be expressed and presented in a way that is readily understood by the intended user;		
	information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;		
	the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice such as national helplines, websites;		
	for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.		
20.	Label and instructions for use		
20.1.	General requirements regarding the information supplied by the manufacturer		

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
N/A	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any		rippiicu	Сотришес
1,711	safety and performance information relevant to the user or any other person, as appropriate. Such information may			
	appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a			
	website, be made available and kept up to date on the website, taking into account the following			
20.1.(a)	The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the			
2011(0)	particular device, its intended purpose and the technical knowledge, experience, education or training of the intended			
	user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where			
	appropriate, supplemented with drawings and diagrams.			
20.1.(b)	The information required on the label shall be provided on the device itself. If this is not practicable or appropriate,			
	some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is			
	not practicable, the information shall be set out on the packaging of multiple devices.			
20.1.(c)	Labels shall be provided in a human-readable format and may be supplemented by machine-readable information,			
	such as radio-frequency identification or bar codes.			
20.1.(d)	Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases			
	instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the			
	manufacturer without any such instructions for use.			
20.1.(e)	Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to			
	a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser			
	who in any case may request further copies to be provided free of charge.			
20.1.(f)	When the device is intended for professional use only, instructions for use may be provided to the user in non-paper			
	format (e.g. electronic), except when the device is intended for near-patient testing.			
20.1.(g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations,			
	contra-indications, precautions or warnings in the information supplied by the manufacturer.			
20.1.(h)	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised			
	symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the			
	harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall			
	be described in the documentation supplied with the device.			
20.1.(i)	In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking			
	account of the nature and quantity of its constituents and the form under which they are present, relevant hazard			
	pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient			
	space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the			
	label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.			
20.1.(j)	The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information,			
	as appropriate, is already made available in the instructions for use.			
20.2.	Information on the label			
N/A	The label shall bear all of the following particulars			
20.2.(a)	the name or trade name of the device;			

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.2.(b)	the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;			
No.	General Safety and Performance Requirements	Applicability	1	Evidence of Compliance
20.2.(c)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;			
20.2.(d)	if the manufacturer has its registered place of business outside the Union, the name of its authorised rep resentative and the address of the registered place of business of the authorised representative;			
20.2.(e)	an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;			
20.2.(f)	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;			
20.2.(g)	the UDI carrier as referred to in Article 24 and Part C of Annex VI;			
20.2.(h)	an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;			
20.2.(i)	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;			
20.2.(j)	where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;			
20.2.(k)	an indication of any special storage and/or handling condition that applies;			
20.2.(l)	where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;			
20.2.(m)	warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;			
20.2.(n)	if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their accessibility (or availability), and where applicable the website address where they can be consulted;			
20.2.(o)	where applicable, any particular operating instructions;			
20.2.(p)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;			
20.2.(q)	if the device is intended for self-testing or near-patient testing, an indication of that fact;			
20.2.(r)	where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;			
20.2.(s)	where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;			

No.	General Safety and Performance Requirements	Applicability		Evidence of Compliance
20.2.(t)	the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate		- 1 1	•
	action to detect any potential risk posed by the devices and detachable components. As far as practicable and			
	appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;			
20.2.(u)	the label for devices for self-testing shall bear the following particulars			
20.2.(u).(i)	the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);			
20.2.(u).(ii)	the need for additional materials for the test to function properly;			
20.2.(u).(iii)	contact details for further advice and assistance.			
N/A	The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.			
20.3.	Information on the packaging which maintains the sterile condition of a device ('sterile packaging')			
N/A	The following particulars shall appear on the sterile packaging			
20.3.(a)	an indication permitting the sterile packaging to be recognised as such,			
20.3.(b)	a declaration that the device is in a sterile condition,			
20.3.(c)	the method of sterilisation,			
20.3.(d)	the name and address of the manufacturer,			
20.3.(e)	a description of the device,			
20.3.(f)	the month and year of manufacture,			
20.3.(g)	an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month			
	and, where relevant, the day, in that order,			
20.3.(h)	an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally			
	opened before use.			
20.4.	Information in the instructions for use			
20.4.1.	The instructions for use shall contain all of the following particulars			
20.4.1.(a)	the name or trade name of the device;			
20.4.1.(b)	the details strictly necessary for the user to uniquely identify the device;			
	the device's intended purpose			
20.4.1.(c).(i)	what is detected and/or measured;			
	its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);			
20.4.1.(c).(iii)	the specific information that is intended to be provided in the context of			
N/A	a physiological or pathological state;			
N/A	congenital physical or mental impairments;			
N/A	the predisposition to a medical condition or a disease;			
N/A	the determination of the safety and compatibility with potential recipients;			
N/A	the prediction of treatment response or reactions;			
N/A	the definition or monitoring of therapeutic measures;			
20.4.1.(iv)	whether it is automated or not;			
20.4.1.(v)	whether it is qualitative, semi-quantitative or quantitative;			

No.	General Safety and Performance Requirements	Applicability	1	Evidence of Compliance
	the type of specimen(s) required;			
20.4.1.(vii)	where applicable, the testing population; and			
20.4.1.(viii)	for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for			
	which it is a companion test.			
No.	General Safety and Performance Requirements	Applicability	1	Evidence of Compliance
20.4.1.(d)	an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;			
20.4.1.(e)	the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);			
20.4.1.(f)	the test principle;			
20.4.1.(g)	a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);			
20.4.1.(h)	a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;			
20.4.1.(i)	a list of materials provided and a list of special materials required but not provided;			
20.4.1.(j)	for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment			
N/A	information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or			
N/A	information on any known restrictions to combinations of devices and equipment.			
20.4.1.(k)	an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;			
20.4.1.(l)	in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;			
20.4.1.(m)	if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;			
20.4.1.(n)	information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate			
20.4.1.(n).(i)	warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,			
20.4.1.(n).(ii)	warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,			

No.		Applicability	Evidence of Compliance
	warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably		
	foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or		
	other procedures such as electromagnetic interference emitted by the device affecting other equipment,		
	precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine		
	disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,		
` ' ` '	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be		
	consistent across the Union,		
	if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection,		
	decontamination, packaging and, where appropriate, the validated method of re-sterili sation. Information shall be		
	provided to identify when the device should no longer be reused, such as signs of material degradation or the		
	maximum number of allowable reuses;		
20.4.1.(o)	any warnings and/or precautions related to potentially infectious material that is included in the device;		
20.4.1.(p)	where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on		
	radiation safety, or particular qualifications of the intended user;		
20.4.1.(q)	conditions for collection, handling, and preparation of the specimen;		
20.4.1.(r)	details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final		
	assembly, calibration, etc., for the device to be used as intended by the manufacturer;		
20.4.1.(s)	the information needed to verify whether the device is properly installed and is ready to perform safely and as		
	intended by the manufacturer, together with, where relevant		
N/A	details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;		
N/A	identification of any consumable components and how to replace them;		
N/A	information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;		
N/A	methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.		
20.4.1.(t)	where applicable, recommendations for quality control procedures;		
20.4.1.(u)	the metrological traceability of values assigned to calibrators and control materials, including identification of applied		
	reference materials and/or reference measurement procedures of higher order and information regarding maximum		
	(self-allowed) batch to batch variation provided with relevant figures and units of measure;		
20.4.1.(v)	assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing		
	shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch		
	to batch variation provided with relevant figures and units of measure;		
20.4.1.(w)	analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision		
	(repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and		
	measurement range, (information needed for the control of known relevant interferences, cross-reactions and		
	limitations of the method), measuring range, linearity and information about the use of available reference		
	measurement procedures and materials by the user;		
20.4.1.(x)	clinical performance characteristics as defined in Section 9.1 of this Annex;		

No.		Applicability	Standards Applied	Evidence of Compliance
	the mathematical approach upon which the calculation of the analytical result is made;			
` '	where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic			
	specificity, positive and negative predictive value;			
_ ` ′	where relevant, reference intervals in normal and affected populations;			
` '	information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of			
	specimen) that may affect the performance of the device;			
` /	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the			
	consumables used with it, if any. This information shall cover, where appropriate			
20.4.1.(ac).(i)	infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human			
	origin;			
20.4.1.(ac).(ii)	environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);			
20.4.1.(ac).(iii)	physical hazards such as explosion.			
20.4.1.(ad)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of			
	business at which he can be contacted and its location be established, together with a telephone number and/or fax			
	number and/or website address to obtain technical assistance;			
20.4.1.(ae)	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision			
	of the instructions for use, with a clear indication of the introduced modifications;			
20.4.1.(af)	a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the			
	manufacturer and the competent authority of the Member State in which the user and/or the patient is established;			
20.4.1.(ag)	where device kits include individual reagents and articles that may be made available as separate devices, each of			
	these devices shall comply with the instructions for use requirements contained in this Section and with the			
	requirements of this Regulation;			
20.4.1.(ah)	for devices that incorporate electronic programmable systems, including software, or software that are devices in			
	themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures,			
	including protection against unauthorised access, necessary to run the software as intended.			
20.4.2.	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following			
	principles			
20.4.2.(a)	details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation			
	and information on how to run the test and interpret the results;			
20.4.2.(b)	specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to			
	enable the user to use the device and to understand the result(s) produced by the device;			
20.4.2.(c)	the device's intended purpose shall provide sufficient information to enable the user to understand the medical context			
	and to allow the intended user to make a correct interpretation of the results;			
20.4.2.(d)	the results shall be expressed and presented in a way that is readily understood by the intended user;			

No.	General Safety and Performance Requirements	Applicability	Evidence of Compliance
20.4.2.(e)	information shall be provided with advice to the user on action to be taken (in case of positive, negative or		
	indeterminate result), on the test limitations and on the possibility of false positive or false negative result.		
	Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation,		
	infection, exercise, fasting, diet or medication;		
20.4.2.(f)	the information provided shall include a statement clearly directing that the user should not take any decision of		
	medical relevance without first consulting the appropriate healthcare professional, information on disease effects and		
	prevalence, and, where available, information specific to the Member State(s) where the device is placed on the		
	market on where a user can obtain further advice such as national helplines, websites;		
20.4.2.(g)	for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition,		
	the information shall specify that the patient should only adapt the treatment if he has received the appropriate		
	training to do so.		

## Applied Standards, Common Specifications, Guidelines, and Regulations

## **International Standards and Common Specifications**

Number	Version	Title
Test	One	Two

## **International Guidance and Regulations**

Number	Version	Title
Test	One	Two