TRINZO

IVDR GSPR Checklist



Under the IVD Regulation, the General Safety and Performance Requirements (GSPRs) of Annex I are more demanding that their IVD Directive counterparts, the Essential Requirements. Where the IVD Directive included 13 Essential Requirements, the IVD Regulation has 20 requirements that must be considered.

IVD manufacturers must demonstrate conformity with the GSPRs, including the use of justification, validation, and verification of the solutions used to meet the applicable requirements. For those requirements which are considered to not be applicable, a justification of this fact must be provided.

The completed checklist must include:

- The general safety and performance requirements that apply to the device and an explanation as to why others to not apply;
- The method or methods use to demonstrate conformity with each appliable requirement;
- The standards, common specifications, or other solutions applied to meet the requirement;
- The precise identity of the controlled documents offering evidence of conformity with each standard,
- common specification or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence with the full technical documentation.

The GSPRs are separated into three chapters:

Chapter I (GSPRs 1 – 8) examines the General Requirements related to risk management, risk control, and benefit-risk. The eight GSPRs in this chapter apply to all devices.

Chapter II (GSPRs 9 – 19) deals with Requirements Regarding Performance, Design, and Manufacture. This chapter is broken down into the following subsections:

- Performance characteristics
- Chemical, physical and biological properties
- Infection and microbial contamination
- Devices incorporating materials of biological origin
- Construction of devices and interaction with their environment
- Devices with a measuring function
- Protection against radiation
- Electronic programmable systems
- Devices connected to or equipped with an energy source
- Protection against mechanical and thermal risks
- Protection against the risks posed by devices intended for self-testing or near-patient testing.

Chapter III (GSPR 20) focuses on Requirements Regarding Information Supplied With The Device, specially the following aspects:

- Label and instructions for use
- General requirements regarding the information supplied by the manufacturer
- Inforamtion on the label
- Information on the packaging which maintains the sterile condition of a device
- Information in the instructions for use.

The applicability of the requirements listed in Chapters II and III should be examined on a case-by-case basis, depending on the nature of the device in question.

Guidance for using the GSPR checklist template:

Sample text is in blue italics.

The text in the "**Methods Applied**" column is sample text only. The text should be expanded upon, or amended to accurately reflect the individual manufacturer's specific processes and procedures. • Standards and solutions referenced are suggestions only – the list is non-exhaustive and the applicable standards must be determined by the manufacturer according to their devices.

GSPRs 1-8 and GSPR 9.2 are applicable to all devices. The applicability of the remaining GSPRs must be determined by the device manufacturer according to their individual devices. For those GSPRs that are not applicable, a justification should be included in the "Evidence" column.

As much detail as possible should be given on the location of evidence, e.g. where Risk Management File (RMF) is referenced, the specific section of the file addressing that particular risk should be identified; where instructions for Use (IFU) is referenced, the applicable section of the IFU should be identified.

MDCG guidance documents should be included in the Standards and Solutions column where appropriate. They have not been included in this checklist given that they are constantly evolving and going through updates.

Suggested Standards		
Standard reference	**Title**	**Typically covers (non-exhaustive)**
ISO 5725-1	Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions	Analytical performance studies (parameters relating to trueness and precision).
ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Requirements for handling instructions on device packaging
ISO 11014	Safety data sheet for chemical products – content and order of sections	Chemical safety
ISO 11135	Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices	Devices sterilised by ethylene oxide
ISO 11137-1	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Devices sterilised by radiation
ISO 11737-1	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products	Devices sterilised by microbiological methods
ISO 11737-2	Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Devices sterilised by microbiological methods
ISO 13408	Aseptic processing of health care products – Part 6: Isolator systems	Devices incorporating isolator systems.
ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes	Design and manufacturing
ISO 13532	General requirements for in vitro diagnostic medical devices for self-testing	Self-testing IVDs
ISO 13612	Performance evaluation of in vitro diagnostic medical devices	Performance evaluation
ISO 13641	Elimination or reduction of risk of infection related to in vitro diagnostic reagents	Infection risk

Suggested Standards		
Standard reference	**Title**	**Typically covers (non-exhaustive)**
ISO 13975	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects	Acceptance testing
ISO 14136	Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures	IVD performance assessment
ISO 14937	Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	General sterilisation requirements
ISO 14971	Medical devices — Application of risk management to medical devices	Risk; benefit-risk
ISO 15193	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures	Biological samples
ISO 15194	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation	Biological samples
ISO 15223	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Use of symbols in IFU and labels
ISO 17511	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	Requirements for assurance of metrological traceability of calibrator and control materials.
ISO 17665	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	Devices sterilised using moist heat
ISO 18113-1	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements	Labelling requirements

Suggested Standards		
Standard reference	**Title**	**Typically covers (non-exhaustive)**
ISO 18113-2	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use	Labelling requirements for professional use reagents
ISO 18113-3	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use	Labelling requirements for professional use instrumentation
ISO 18113-4	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing	Labelling requirements for self-testing reagents
ISO 18113-5	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing	Labelling requirements for self-testing instrumentation
ISO 18153	In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials	Metrological traceability
ISO 20916	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice	Clinical performance, where a clinical study has been carried out.
ISO 21151	In vitro diagnostic medical devices — Requirements for international harmonisation protocols establishing metrological traceability of values assigned to calibrators and human samples	Requirements for assurance of metrological traceability of calibrator and control materials.
ISO 23640	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents	In use, shelf life, and shipping stability studies.
ISO 25424	Sterilization of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilization process for medical devices	Devices sterilised by low temperature steam and formaldehyde

Suggested Standards		
Standard reference	**Title**	**Typically covers (non-exhaustive)**
IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements	IVD instrumentation
IEC 61326	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment	IVD instrumentation
IEC 62304	Medical device software — Software life cycle processes	Software requirements
IEC 62366	Medical devices — Part 1: Application of usability engineering to medical devices	Usability, during normal use
ISTA 2A	International Safe Transit Association Test Procedure	Shipping / Transport stability

The current list of all standards harmonised to (EU) IVDR 2017/746 can be found **here**

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter I – General Requirements					
1	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.	*Y*	*The device has been designed in accordance with company procedures which ensure the GSPR requirements have been met. Testing has been conducted as applicable.*	*ISO 13485* *IEC 62366* *ISO 14971* *ISO 13612*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *PER Ref: XXX* *IFU Ref: XXX* *Usability Engineering File Ref: XXX*
2	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.	*Y*	*Risk management activities have been performed to identify, eliminate, or reduce any risks.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *RMF Ref: XXX* *Risk Management Procedure Ref: XXX*
3	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: (a) establish and document a risk management plan for each device; (b) identify and analyse the known and foreseeable hazards associated with each device; (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; (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 (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.	*Y*	*An approved risk management system has been developed. The risk management procedure details the criteria for reviewing the risk management process.*	*ISO 13485* *IEC 62366* *ISO 14971*	*ISO 13485 Certificate* *RMF Ref: XXX* *Risk Management Procedure Ref: XXX* *Usability Engineering File Ref: XXX*
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	*Y*	*The devices are manufactured to conform to safety principles through risk analysis/assessment.* *The Risk Management procedure describes*	*ISO 14971* *ISO 18113-X*	*Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IFU Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter I – General Requirements					
	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: **(a)** eliminate or reduce risks as far as possible through safe design and manufacture; **(b)** where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and **(c)** provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks.		*the criteria for residual risk acceptability. Each device is manufactured in line with approved procedures, with in-process checks performed. There are no residual risks requiring notification to users OR Users are notified of residual risks via XXX.*		
5	In eliminating or reducing risks related to use error, the manufacturer shall: **(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 **(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).	*Y*	*Risks related to ergonomic features and safety elements are considered during the risk assessment. The device usability has been verified via usability testing.*	*ISO 14971 IEC 62366*	*Risk Management Procedure Ref: XXX RMF Ref: XXX Usability Engineering File Ref: XXX*
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.	*Y*	*Product risks throughout the lifetime of the device and during normal conditions of use, are considered during the product risk assessment. Shelf life testing was carried out to confirm that the device performs according to its intended uses for the defined lifecycle.*	*ISO 14971 ISO 23640 ISO 13612*	*Risk Management Procedure Ref: XXX RMF Ref: XXX Stability Report Ref: PER Ref: XXX*
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.	*Y*	*Shipping and shelf life studies are carried out to confirm that the device is not adversely affected during transport and storage.*	*ISO 13485 ISO 14971 ISO 18113-X ISO 23640 ISTA 2A*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX IFU Ref: XXX Label Ref: XXX Transport Stability Report Ref: XXX Packaging Process: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter I – General Requirements					
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.	*Y*	*An approved risk management system is in place. Risk assessments are performed to identify and minimise risks.* *The Risk Management procedure describes the criteria for residual risk acceptability. Performance evaluation was performed to evaluate any risks that may be associated with the use of the device, and concluded that the benefit-risk profile is acceptable.*	*ISO 13485* *ISO 14971* *ISO 13612*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *PER Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter II – Requirements Regarding Performance, Design and Manufacture					
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 and in particular, where applicable:		*This device is designed and manufactured to provide information (e.g. concerning a physiological or pathological process or state; concerning congenital physical or mental impairments; concerning the predisposition to a medical condition or a disease; to determine the safety and compatibility with potential recipients; to predict treatment response orreactions; to define or monitoring therapeutic measures). Achievement of this is confirmed via product verification, performance evaluation and validation testing.*	*ISO 13485* *ISO 62366* *ISO 13612*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Manufacturing Instructions: XXX* *Quality Control Records: XXX PER Ref: XXX* *Usability Engineering File Ref: XXX*
	(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 analytical performance parameters (XXX) are achieved and the results are documented in the Analytical Performance Report (APR).*	*ISO 13485* *ISO 5725-1* *ISO 13612* *ISO 13975* *ISO 14136* *ISO 15193* *ISO 15194* *ISO 17511* *ISO 13641*	*ISO 13485 Certificate* *Quality Manual* *APR Ref: XXX*
	(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 clinical performance parameters (XXX) are achieved and the results are documented in the Clinical Performance Report (CPR).*	*ISO 13485* *ISO 20916*	*ISO 13485 Certificate* *Quality Manual* *CPR Ref: XXX*
9.2	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.	*Y*	*Shelf life stability studies have been carried out and have confirmed that the device will perform as intended for its lifetime.*	*ISO 23640* *ISO 13612*	*Stability Report Ref: XXX* *PER Ref: XXX* *Label Ref: XXX* *IFU Ref: XXX*
9.3	Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability		*The metrological traceability of the associated calibrators and controls is*	*ISO 17511* *ISO 21151*	*APR Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter II – Requirements Regarding Performance, Design and Manufacture					
	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.		*recorded in the Analytical Performance Report. The values assigned are assured to certified reference materials.*		
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:				
	(a) for devices for self-testing, performances obtained by laypersons;		*Usability studies have confirmed that the characteristics and performances of the device are not affected when the device is used by laypersons.*	*IEC 62366* *ISO 13532* *ISO 13612*	*Usability Engineering File Ref: XXXPER Ref: XXX*
	(b) for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).		*Usability studies have confirmed that the characteristics and performances of the device are not affected when the device is used in near-patient testing environments.*	*IEC 62366* *ISO 13612*	*Usability Engineering File Ref: XXXPER Ref: XXX*
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. 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.		*Product verification and validation studies confirm that the performance characteristics and requirement associated with this device are fulfilled. The risk of impairment of performance due to incompatibility between materials and specimens or analytes is assessed as part of the device risk management activities and is found to be acceptable.*	*ISO 13485* *ISO 14971* *ISO 13612*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Manufacturing Instructions: XXX* *Quality Control Records: XXX APR Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Verification and Validation Report*
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.		*Contamination risks are assessed during the device risk management activities and are found to be acceptable.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter II – Requirements Regarding Performance, Design and Manufacture					
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]).		*Risks posed by substances and particles that may be released from the device are assessed as part of the device risk management activities and are found to be acceptable.* *Manufacturing components are assessed according the REACH and CLP regulations.*	*ISO 13485* *REACH Regulation* *CLP Regulation* *ISO 11014* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Safety Data Sheet Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
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.		*Risks related to the unintentional ingress of substances into the device are assessed during the device risk assessment and are found to be acceptable.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
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: (a) allow easy and safe handling; (b) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary (c) prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.		*Risks of infection to the user are assessed during the device risk assessment and are found to be acceptable.* *The device is designed to allow safe handling, the reduction of microbial leakage and exposure during use, and microbial contamination of the device itself.*	*ISO 13485* *ISO 14971* *ISO 14937* *ISO 11135* *ISO 11137-1* *ISO 11737-2* *ISO 25424* *ISO 11737-1* *ISO 17665* *ISO 15223*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Sterility Verification and Validation Report* *Label Ref: XXX*
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.		*This sterility of this device is maintained and confirmed throughout transport and storage, as recorded in the design and development file, sterility report, and transport stability report.*	*ISO 14937* *ISO 11135* *ISO 11137-1* *ISO 11737-2* *ISO 25424* *ISO 11737-1* *ISO 17665* *ISO 780* *ISO 23640* *ISTA 2A*	*Design and Development FileSterility Verification and Validation Report* *Packaging Process XXX* *Manufacturing Instructions: XXX Transport Stability Report Ref: XXX Label Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter II – Requirements Regarding Performance, Design and Manufacture					
				ISO 15223	
11.3	Devices labelled as sterile shall be processed, manufactured, packaged and sterilised by means of appropriate, validated methods.		*This device is manufactured and packaged according to approved processes. Appropriate cleanroom validation is carried out in the manufacturing premises. This device is sterilised according to ISO XXXXX.*	*ISO 14937 ISO 11135 ISO 11137-1 ISO 11737-2 ISO 25424 ISO 11737-1 ISO 17665 ISO 15223*	*Design and Development File Sterility Verification and Validation Report Manufacturing Instructions: XXX Packaging Process XXX Cleanroom validation Label Ref: XXX*
11.4	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.		*This device is manufactured and packaged according to approved processes. Appropriate cleanroom validation is carried out in the manufacturing premises.*	*ISO 14937 ISO 11135 ISO 11137-1 ISO 11737-2 ISO 25424 ISO 11737-1 ISO 17665*	*Sterility Verification and Validation Report Manufacturing Instructions: XXX Packaging Process XXX Cleanroom validation*
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.		*The packaging process for this device is sufficient for ensuring that the requirements for device integrity, cleanliness, and sterility are achieved.*	*ISO 14937 ISO 11135 ISO 11137-1 ISO 11737-2 ISO 25424 ISO 11737-1 ISO 17665*	*Design and Development FileVerification and Validation Report Packaging Process XXX*
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.		*The label contains information to identify the device as sterile. Similar/identical non-sterile devices (XXX) are clearly labelled as such to allow them to be appropriately distinguished from the sterile device.*	*ISO 18113-X ISO 15223*	*Sterile Device Label Ref: XXXNon-sterile Device Label Ref: XXX*
12	Devices incorporating materials of biological origin				
	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. 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		*This device contains material of XXX origin. A certificate of origin is available. The supplier is qualified and on the critical supplier list.*	*ISO 13485 ISO 14971 Directive 2004/23/EC Directive 2002/98/EC Directive 2006/17/EC*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX Manufacturing Instructions: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
	Chapter II – Requirements Regarding Performance, Design and Manufacture				
	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.				*Verification and Validation Report*
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.		*The system as a whole as part of which the device is intended to be used is verified as being safe and performing as intended. Restrictions (XXX) are referenced on the label/IFU.*	*ISO 18113-X* *ISO 15223* *ISO 14971* *ISO 62366*	*Design and Development File* *Verification and Validation Report* *Label Ref: XXX* *IFU Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF File Ref: XXX* *Usability Engineering File Ref: XXX*
13.2	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:				
	(a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;		*Risks related to injury related to physical features are assessed as part of the risk management activities and are found to be acceptable.*	*ISO 13485* *ISO 14971* *ISO 61010-1*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Verification and Validation Report*
	(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;		*Risks related to reasonably foreseeable external influences (XXX) are assessed as part of the risk management activities and are found to be acceptable.*	*ISO 13485* *ISO 14971* *ISO 61010-1*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Verification and Validation Report*
	(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;		*Risks associated with the use of the device when it comes into contact with materials and substances as part of its normal use are assessed as part of the risk management*	*ISO 13485* *ISO 14971* *ISO 61010-1*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Risk Management Procedure Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter II – Requirements Regarding Performance, Design and Manufacture					
			activities and are found to be acceptable.		*RMF Ref: XXX Verification and Validation Report*
	(d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;		*Risks related to negative interaction between software and the IT environment are assessed as part of the risk management activities and found to be acceptable.*	*ISO 13485 ISO 14971 ISO 62304 ISO 61010-1*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX Verification and Validation Report*
	(e) the risks of accidental ingress of substances into the device;		*Risks of accidental ingress of substances are assessed as part of the risk management activities and found to be acceptable.*	*ISO 13485 ISO 14971 ISO 61010-1*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX Verification and Validation Report*
	(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;		*Risks related to incorrect identification of specimens and erroneous results due to the presentation of specimen receptacles, removable parts, and accessories are assessed as part of the risk management activities and found to be acceptable.*	*ISO 13485 ISO 14971 ISO 61010-1*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX Verification and Validation Report*
	(g) the risks of any foreseeable interference with other devices.		*Risks of interference with other devices are assessed as part of the risk management activities and found to be acceptable.*	*ISO 13485 ISO 14971 ISO 61010-1*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX Verification and Validation Report*
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		*Risks of fire and explosion during normal use are assessed as part of the risk management activities and found to be acceptable.*	*ISO 13485 ISO 14971 IEC 61010-1 ISO 15223*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management*

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	association with flammable or explosive substances or substances which could cause combustion.				*Procedure Ref: XXX* *RMF Ref: XXX* *IFU/Manual Ref: XXX* *Label Ref: XXX*
13.4	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.		*The safe and effective adjustment, calibration, and maintenance of the device is assessed and examined during risk management activities, and usability engineering studies, and is found to be acceptable.*	*ISO 13485* *ISO 62366* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Usability Engineering File Ref: XXX Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
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.		*Interoperability between this device and XXX device is confirmed as being safe and reliable. This documented in the verification and validation report.*	*ISO 13485* *ISO 62366*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Verification and Validation Report Usability Engineering File Ref: XXX*
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.		*Instructions on the disposal of this device can be found in the IFU (Section: XXX). These instructions have been created in line with the relevant Directives (XXX) and Regulations (XXX) and detail can be found in the Design and Development File.*	*ISO 13485* *Directive 2012/19/EU (WEEE)* *Directive 2011/65/EU (RoHS) REACH Regulation* *CLP Regulation* *ISO 18113-X* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *IFU Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
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 environmental conditions in which the devices are intended to be used.		*The XXX scale that is part of this device is designed and manufactured in line with ergonomic principles. Usability Engineering studies have confirmed its suitability for its intended purpose, users and environment of use.*	*ISO 13485* *IEC 62366*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Usability Engineering File Ref: XXX*
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		*Devices are designed and manufactured in such a way that analytical performance parameters (such as, analytical*	*ISO 13485* *ISO 13612*	*ISO 13485 Certificate* *Quality Manual* *Design and*

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	Annex I, taking into account the intended purpose of the device.		*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) are achieved. Results are recorded in the Analytical Performance Report.*		*Development File Manufacturing Instructions: XXX APR Ref: XXX*
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]).		*The measurements made by the device are expressed as XXX.*	*Directive 80/181/EEC*	*Design and Development File*
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.		*IEC 61010-1 testing of the device, has confirmed that radiation exposure is at an acceptable level according to the intended use of the device.*	*ISO 13485 IEC 61010-1 ISO 14971 ISO 62366*	*ISO 13485 Certificate Quality Manual Design and Development File IEC Report Ref: XXX Risk Management Procedure Ref: XXX RMF Ref: XXX Usability Engineering File Ref: XXX*
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: (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 (b) fitted with visual displays and/or audible warnings of such emissions.		*The device is equipped with features to control and adjust the radiation levels emitted by the device. A suitable warning (XXX) is present to alert users to emissions.*	*ISO 13485 IEC 61010-1 ISO 14971*	*ISO 13485 Certificate Quality Manual Design and Development File Verification and Validation Report IEC Report Ref: XXX Risk Management Procedure Ref: XXX RMF Ref: XXX*
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.		*The device IFU contains a section (XXX) on the nature of the radiation emitted, the means of user protection, instruction on avoiding misuse and reducing installation risks as far as possible, and information on acceptance criteria, performance testing, and the applicable maintenance procedure.*	*ISO 13485 ISO 18113-X IEC 61010-1 ISO 14971*	*ISO 13485 Certificate IFU / Manual Ref: XXX IEC Report Ref: XXX Risk Management Procedure Ref: XXX RMF Ref: XXX*

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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.		*The repeatability, reliability and performance of the device is confirmed via verification and validation activities and testing according to IEC 61010-1 and ISO 62304.*	*ISO 13485* *ISO 62304* *IEC 61010-1*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Verification and Validation Report IEC Report Ref: XXX*
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.		*The device software is developed and manufactured in accordance with SOTA and with the principles of development life cycle, risk management, and verification and validation in mind.*	*ISO 13485* *ISO 14971* *ISO 62304* *ISO 13612* *IEC 61010-1*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Manufacturing Instructions: XXX* *Verification and Validation Report Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *PER Ref: XXX* *IEC Report Ref: XXX*
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).		*The device software is designed with the specific features of the mobile platform (XXX) and the environment of use in mind.*	*ISO 13485* *ISO 62304* *ISO 13612* *IEC 61010-1* *ISO 18113-X*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Manufacturing Instructions: XXX* *Verification and Validation ReportPER Ref: XXX* *IEC Report Ref: XXX* *IFU / Manual Ref: XXX*
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.		*Minimum requirements for hardware, and IT networks and security measures are provided in the IFU.*	*ISO 62304* *ISO 18113-X* *ISO 14971*	*IFU / Manual Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IEC Report Ref: XXX*
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 related to single fault conditions are assessed as part of the risk*	*IEC 61010-1* *ISO 14971*	*IEC Report Ref: XXX* *Risk Management*

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	risks.		*management process and are found to be acceptable.*	*ISO 62366*	*Procedure Ref: XXX* *RMF Ref: XXX* *Usability Engineering File Ref: XXX*
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.		*A display is present on the device to indicate the power supply capacity OR* *An alarm is present on the device to indicate when the power supply is low before the supply level becomes critical.*	*IEC 61010-1* *ISO 14971*	*Verification/Verification and Validation Report* *IEC Report Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
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.		*Risks related electromagnetic interference which could impair the operation of the subject device or other devices, are assessed as part of the risk management process and are found to be acceptable.*	*ISO 13485* *IEC 61010-1* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *IEC Report Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
17.4	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.		*IEC 61010-1 testing of the device has confirmed that there is an appropriate level of intrinsic immunity to electromagnetic interference.*	*ISO 13485* *IEC 61010-1* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *IEC Report Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
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.		*Risks related to accidental electric shocks to the user during normal use and in the event of a single fault condition are assessed as part of the risk management process and are found to be acceptable.*	*ISO 13485* *IEC 61010-1* *ISO 14971* *ISO 18113-X*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *IEC Report Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IFU / Manual Ref: XXX*
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.		*The potential for mechanical risks is assessed as part of the risk management*	*ISO 13485* *IEC 61010-1*	*ISO 13485 Certificate* *Quality Manual*

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			activities and is found to be acceptable.	*ISO 14971*	*Design and Development File IEC Report Ref: XXX Risk Management Procedure Ref: XXX RMF Ref: XXX*
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.		*Verification and Validation testing has confirmed that the device is stable under normal operating conditions, and throughout the device lifetime.*	*IEC 61010-1 ISO 14971 ISO 62366*	*Verification and Validation ReportShelf life Stability Report Risk Management Procedure Ref: XXX RMF Ref: XXX IEC Report Ref: XXX Usability Engineering File Ref: XXX*
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. 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.		*The potential for risks due to the presence of moving parts, break up, detachment, or leakage of substances is assessed as part of the risk management activities and is found to be acceptable.* *Protective guards are secure and do not interfere with normal operation of routine maintenance of the device.*	*ISO 13485 ISO 14971 IEC 61010-1*	*ISO 13485 Certificate Risk Management Procedure Ref: XXX RMF Ref: XXX Design and Development File IEC Report Ref: XXX*
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.		*Risks related vibration generated by the device are assessed as part of the risk management activities and are found to be acceptable.*	*ISO 13485 ISO 14971 IEC 61010-1*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX IEC Report Ref: XXX*
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.		*Risks related to emitted noise are assessed as part of the risk management activities and are found to be acceptable.*	*ISO 13485 ISO 14971 IEC 61010-1*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX IEC Report Ref: XXX*

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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.		*The potential for risks related to terminals and connectors to energy supplies handled by a device user is assessed as part of the risk management activities and is found to be acceptable.*	*ISO 13485* *ISO 14971* *IEC 61010-1*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IEC Report Ref: XXX*
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. 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.		*The potential for risks related to errors made when fitting or refitting parts is assessed as part of the risk management activities and is found to be acceptable. Those risks that cannot be designed out are communicated to the user via inforamtion on the parts.*	*ISO 13485* *ISO 14971* *IEC 61010-1* *ISO 18113-X* *ISO 62366*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IEC Report Ref: XXX* *Label Ref: XXX* *IFU / Manual Ref: XXX* *Usability Engineering File Ref: XXX*
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.		*The potential for dangerous temperatures under normal use conditions is assessed as part of the risk management activities and is found to be acceptable.*	*IEC 61010-1* *ISO 14971*	*IEC Report Ref: XXX* *Verification/Verification and Validation Report* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
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.		*The device is designed and manufactured to ensure that the intended user can use as intended. Device usability is verified according to the usability engineering file.* *The information provided with the device is created with the intended user's background in mind, and designed to ensure that instructions are readily understood by the user.*	*ISO 13485* *ISO 14971* *ISO 18113-X* *IEC 62366* *ISO 13532*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Usability Engineering File Ref: XXX*

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19.2	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to:				
	(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 (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.		*Usability testing has confirmed thatthe device can be used safely at all stages of the procedure by the appropriate user.* *The potential for errors in the handling of the device and the specimen, and the interpretation of results was assessed as part of the risk management activities and is found to be acceptable.*	*ISO 13485* *IEC 62366* *ISO 14971* *ISO 13532* *ISO 18113-X*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Usability Engineering File Ref: XXX Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IFU Ref: XXX*
19.3	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user:				
	(a) can verify that, at the time of use, the device will perform as intended by the manufacturer; and (b) be warned if the device has failed to provide a valid result.		*XXX allows the user to verify that the device is performing as intended.* *A warning is provided in the form of XXX if the device has failed to provide a valid result.*	*ISO 14971* *ISO 13532* *IEC 62366* *ISO 18113-X*	*Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IFU / Manual Ref: XXX* *Usability Engineering File Ref: XXX IFU Ref: XXX*

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Chapter III – Requirements Regarding Information Supplied With The Device					
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 and kept up to date on the website, taking into account the following:				
	(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.		*The labelling and IFU is written and formatted with the knowledge and experience of the intended user in mind.*	*ISO 18113-X* *ISO 15223*	*IFU Ref: XXX* *Label Ref: XXX*
	(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.		*The information that is provided on the device label is also provided on the device itself.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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.		*Labels are provided in human readable format.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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.		*Instructions for use are provided with the device.*	*ISO 18113-X* *ISO 15223*	*IFU Ref: XXX*
	(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.		*A single copy of the IFU is provided with the device and additional copies are available upon request.*	*ISO 18113-X*	*IFU Ref: XXX*

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	(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.		*The IFU is provided in electronicformat OR The IFU is provided in paper format.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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.		*Residual risks are communicated in the IFU.*	*ISO 14971 ISO 18113-X ISO 15223*	*Risk Management Procedure Ref: XXX RMF Ref: XXX IFU Ref: XXX Label Ref: XXX*
	(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.		*Symbols according to harmonised standard ISO 15223 are used in the information provided with the device.*	*ISO 18113-X ISO 15223*	*IFU Ref: XXX Label Ref: XXX*
	(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.		*The labelling requirements of Regulation 1272/2008 are applied to the device labelling and the IFU.*	*ISO 18113-X ISO 15223*	*IFU Ref: XXX Label Ref: XXX*
	(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.		*A safety data sheet is provided, which complies with the provisions of Regulation 1907/2006.*	*ISO 11014 ISO 18113-X*	*IFU Ref: XXX SDS Ref: XXX*
20.2	Information on the label The label shall bear all of the following particulars:				
	(a) the name or trade name of the device;		*The name of the device is present on the label.*	*ISO 18113-X*	*Label Ref: XXX*

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	(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;		*The intended purpose of the device is present on the label.*	*ISO 18113-X*	*Label Ref: XXX*
	(c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;		*The manufacturer's registered name and address is present on the device label.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(d) if the manufacturer has its registered place of business outside the Union, the name of its authorised representative and the address of the registered place of business of the authorised representative;		*The name and address of the authorised representative is present on the device label.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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;		*A reference to the device being an in vitro diagnostic medical device is present on the device label OR A reference to the device being a device for performance study is present on the device label.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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;		*The lot number OR serial number is present on the device label, and is preceded by the appropriate symbol.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(g) the UDI carrier as referred to in Article 24 and Part C of Annex VI;		*The UDI carrier is present on the device label.*	*MDCG 2018-1* *ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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;		*The expiration date of the device is present on the device label.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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;		*The manufacturing date is present on the label.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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;		*The quantity of the contents of the packaging is referenced on the device label in weight OR volume OR count.*	*ISO 18113-X*	*Label Ref: XXX*

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	(k) an indication of any special storage and/or handling condition that applies;		*Storage conditions are present on the device label.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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;		*The sterile nature of the device and its sterilisation method are referenced on the device label.*	*ISO 14937* *ISO 11135* *ISO 11137-1* *ISO 11737-2* *ISO 25424* *ISO 11737-1* *ISO 17665* *ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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;		*Information on the warnings and precautions related to this device are present on the device label.*	*ISO 18113-X* *ISO 15223*	*IFU Ref: XXX* *Label Ref: XXX*
	(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;		*The instructions for use are provided in paper form. OR Instructions on accessing the IFU are present on the device label.*	*ISO 18113-X*	*Label Ref: XXX*
	(o) where applicable, any particular operating instructions;		*Operating instructions are present on the device label.*	*ISO 18113-X*	*Label Ref: XXX*
	(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;		*A "single-use" symbol is present on the device label. OR This device is not intended for single use.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(q) if the device is intended for self-testing or near patient testing, an indication of that fact;		*Reference to the self-testing nature of the device is present on the label. OR Reference to the near patient testing nature of the device is present on the label.*	*ISO 18113-X*	*Label Ref: XXX*
	(r) where rapid assays are not intended for self testing or near-patient testing, the explicit exclusion hereof;		*An indication is provided on the device label that this rapid assay is not intended for self-testing or near-patient testing.*	*ISO 18113-X*	*Label Ref: XXX*
	(s) where device kits include individual reagents and		*The individual reagents contained in the*	*ISO 18113-X*	*Label Ref: XXX*

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	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;		*kit all comply with the Section 20.2 labelling requirements and with the IVDR requirements.*		
	(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;		*Lot numbers are separately referenced on the labelling of all device components, allowing for appropriate batch traceability.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(u) the label for devices for self-testing shall bear the following particulars: (i) the type of specimen(s) required to perform the test (e.g. blood, urine or saliva); (ii) the need for additional materials for the test to function properly; (iii) contact details for further advice and assistance. The name of devices for self testing shall not reflect an intended purpose other than that specified by the manufacturer.		*As a self-testing device, the required specimen, the need for additional materials to perform the test, and the contact details for further advice are all referenced on the device label.*	*ISO 18113-X*	*Label Ref: XXX*
20.3	Information on the packaging which maintains the sterile condition of a device ('sterile packaging'): The following particulars shall appear on the sterile packaging:				
	(a) an indication permitting the sterile packaging to be recognised as such,		*There is an indication present on the packaging to identify the packaging as sterile.*	*ISO 18113-X* *ISO 15223* *ISO 780*	*Label Ref: XXX*
	(b) a declaration that the device is in a sterile condition,		*A declaration that the device is in a sterile condition is present on the device packaging.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(c) the method of sterilisation,		*The method of sterilisation is referenced on the device packaging.*	*ISO 14937* *ISO 11135* *ISO 11137-1* *ISO 11737-2* *ISO 25424* *ISO 11737-1* *ISO 17665* *ISO 18113-X*	*Label Ref: XXX*

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	(d) the name and address of the manufacturer,		*The name and address of the manufacturer is referenced on the packaging.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(e) a description of the device,		*A description of the device is present on the packaging.*	*ISO 18113-X*	*Label Ref: XXX*
	(f) the month and year of manufacture,		*The month and year of manufacture is referenced on the packaging.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(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,		*The confirmed stability of the device is referenced on the packaging in YYYY-MM-DD.*	*ISO 18113-X* *ISO 15223*	*Label Ref: XXX*
	(h) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.		*An instruction is present on the packaging to check the IFU in the event of damage to, or the unintentional opening of, the device packaging.*	*ISO 18113-X*	*Label Ref: XXX* *IFU Ref: XXX*
20.4	Information in the instructions for use				
20.4.1	The instructions for use shall contain all of the following particulars:				
	(a) the name or trade name of the device;		*The device name is referenced in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*
	(b) the details strictly necessary for the user to uniquely identify the device;		*The name OR device description provided in the IFU allows the user to uniquely identify the device.*	*ISO 18113-X*	*IFU Ref: XXX*
	(c) the device's intended purpose: (iv) what is detected and/or measured; (v) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic); (vi) the specific information that is intended to be provided in the context of: — a physiological or pathological state; — congenital physical or mental impairments; — the predisposition to a medical condition or a disease; — the determination of the safety and		*The intended purpose of the device, including all elements of points (iv) – (xi), is present in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*

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	compatibility with potential recipients; — the prediction of treatment response or reactions; — the definition or monitoring of therapeutic measures; (vii) whether it is automated or not; (viii) whether it is qualitative, semi-quantitative or quantitative; (ix) the type of specimen(s) required; (x) where applicable, the testing population; and (xi) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.				
	(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;		*A reference to the device being an in vitro diagnostic medical device is present in the IFU OR A reference to the device being a device for performance study is present in the IFU.*	*ISO 18113-X* *ISO 15223*	*IFU Ref: XXX*
	(e) the intended user, as appropriate (e.g. self testing, near patient and laboratory professional use, healthcare professionals);		*The intended user of the device is specified in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*
	(f) the test principle;		*The test principle of the device is referenced in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*
	(g) a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);		*The calibrators and controls (XXX) intended to be used with this device are described in the IFU, along with an instruction to only use them with XXX instrument.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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 description of the reagents is included in the IFU, including information on the composition and a statement on the ingredients that might influence measurement. Instruction is also included to only use the reagents with XXX instrument.*	*ISO 18113-X*	*IFU Ref: XXX*
	(i) a list of materials provided and a list of special materials required but not provided;		*A list of the materials provided with the device, and a list of the materials that are required but not provided is present in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*

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	(j) for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment: — information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or — information on any known restrictions to combinations of devices and equipment.		*Information is provided on the identification of devices and equipment intended to be used in combination with this device, along with an indication of known restrictions on device and equipment combinations.*	*ISO 18113-X* *ISO 15223*	*IFU Ref: XXX*
	(k) an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;		*Special storage (XXX) and handling (XXX) conditions are specified in the IFU.*	*ISO 18113-X* *ISO 15223*	*IFU Ref: XXX*
	(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;		*In-use stability information and the associated storage conditions are present in the IFU.*	*ISO 23640* *ISO 18113-X* *ISO 15223*	*Stability Report Ref:* *IFU Ref: XXX*
	(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;		*The sterile nature of the device, its sterilisation method, and instructions to be followed in the event of damage to the sterile packaging before use are all referenced in the IFU.*	*ISO 14937* *ISO 11135* *ISO 11137-1* *ISO 11737-2* *ISO 25424* *ISO 11737-1* *ISO 17665* *ISO 18113-X* *ISO 15223*	*IFU Ref: XXX*
	(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: (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, (ii) warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable externalinfluences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures,		*Information on warnings, precautions and limitations is provided, relating to device malfunction/degradation, exposure to external influences (XXX), interferences, and sensitisation resulting from CMR/endocrine disrupting substances.* *An indication is provided that the device is intended for single use OR Information is provided on the requirements for the safe reuse of the device.*	*ISO 18113-X* *ISO 15223* *ISO 14937* *ISO 11135* *ISO 11137-1* *ISO 11737-2* *ISO 25424* *ISO 11737-1* *ISO 17665*	*IFU Ref: XXX* *Sterility Verification and Validation Report*

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	pressure, humidity, or temperature, (iii) warnings, precautions and/or measuresto 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, (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, (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, (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 sterilisation. 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;				
	(o) any warnings and/or precautions related to potentially infectious material that is included in the device;		*Warnings and precautions related to infectious material (material ref: XXX) are included in the IFU.*	*ISO 18113-X* *ISO 15223*	*IFU Ref: XXX*
	(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;		*The requirements for special facilities (XXX) and special training are referenced in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*
	(q) conditions for collection, handling, and preparation of the specimen;		*The conditions for collection, handling, and preparation of the specimen are described in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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;		*Required preparatory treatment of the device (XXX) is referenced in the IFU.*	*ISO 14937* *ISO 11135* *ISO 11137-1* *ISO 11737-2* *ISO 25424* *ISO 11737-1* *ISO 17665*	*IFU Ref: XXX*

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				ISO 18113-X	
	(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: — 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; — methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.		*Information is provided to allow the user to verify that the device is correctly installed and ready to perform safely, as intended. This includes maintenance requirements, identification and replacement of consumables, calibration requirements, and risk mitigation methods for installation, calibration and servicing activities.*	*ISO 18113-X*	*IFU / Manual Ref: XXX*
	(t) where applicable, recommendations for quality control procedures;		*A recommendation for specific quality control procedures is present in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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;		*Information on the metrological traceability of the related calibrator and control materials (Ref: XXX) are present in the IFU.*	*ISO 17511* *ISO 21151* *ISO 18113-X*	*IFU Ref: XXX*
	(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;		*Information on the assay procedure is included in the IFU, including calculations, interpretation of results, the requirement for confirmatory testing, along with references to batch to batch variation with the relevant data and measurement units.*	*ISO 18113-X*	*IFU Ref: XXX*
	(w) analytical performance characteristics, such asanalytical 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		*Analytical performance characteristics (XXX) are referenced in the IFU.*	*ISO 13612* *ISO 5725-1* *ISO 18113-X*	*APR Ref: XXX* *IFU Ref: XXX*

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	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;				
	(x) clinical performance characteristics as defined in Section 9.1 of this Annex;		*Clinical performance characteristics (such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations) are referenced in the IFU.*	*MDCG 2022-2* *ISO 20916* *ISO 18113-X*	*CPR Ref: XXX* *IFU Ref: XXX*
	(y) the mathematical approach upon which thecalculation of the analytical result is made;		*The mathematical approach used for the calculation of analytical results is referenced in the IFU.*	*ISO 18113-X* *ISO 13612*	*IFU Ref: XXX* *APR Ref: XXX*
	(z) where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;		*Clinical performance characteristics (XXX) are referenced in the IFU.*	*MDCG 2022-2* *ISO 20916* *ISO 18113-X*	*CPR Ref: XXX* *IFU Ref: XXX*
	(aa) where relevant, reference intervals in normal and affected populations;		*Reference intervals are referenced in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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;		*Interfering substances and device limitations are referenced in the IFU.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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: (vii) infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin; (viii) environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation); (ix) physical hazards such as explosion.		*Information is provided in the IFU on safe device disposal including references to infection/microbial, environmental, and physical hazards.*	*ISO 18113-X* *ISO 15223* *Directive 2012/19/EU (WEEE)* *Directive 2011/65/EU (RoHS)*	*IFU Ref: XXX*
	(ad) the name, registered trade name or registered		*The manufacturer's name,*	*ISO 18113-X*	*IFU Ref: XXX*

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	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;		*address, phone number, fax number and website are referenced in the IFU.*	*ISO 15223*	
	(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;		*The revision and date of issue of the instructions for use is present in the IFU, along with a revision table indicating any modifications that have been made.*	*ISO 18113-X* *ISO 15223*	*IFU Ref: XXX*
	(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;		*A notice is present in the IFU that any serious incident in relation to the device should be reported to the relevant parties.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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;		*The individual reagents contained in the kit all comply with the Section 20.4 IFU requirements and with the IVDR requirements.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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.		*Information is provided in the IFU on the minimum requirements for hardware, and IT network characteristics and security measures, in order to allow the device to be used as intended.*	*ISO 62304* *ISO 18113-X*	*IFU Ref: XXX*
20.4.2	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles:				
	(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;		*Detailed information on the test procedure is provided, including reagent preparation, specimen collection and preparation, and instruction on running the test and interpreting the results.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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;		*XXX information is omitted because the other information provided is considered sufficient for the user to understand the test procedure and result.*	*ISO 18113-X*	*IFU Ref: XXX*

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	(c) the device's intended purpose shall providesufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;		*The intended purpose statement provides sufficient information according to the points listed in Annex II, Section 1.1 (c) of IVDR.*	*ISO 18113-X*	*IFU Ref: XXX*
	(d) the results shall be expressed and presented ina way that is readily understood by the intended user;		*The results are expressed in XXX*	*ISO 18113-X*	*IFU Ref: XXX*
	(e) information shall be provided with advice to theuser 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;		*Advice is provided in the IFU on action to be taken according to the result received. Information is also provided on test limitations and possibility of false results, along with the applicable factors affecting the result (XXX).*	*ISO 18113-X*	*IFU Ref: XXX*
	(f) the information provided shall include astatement 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;		*The IFU contains a statement instructing the user not to make any medical decisions without consulting a healthcare professional. Information is provided on disease effects and prevalence, as well as suggested resources (website XXX) for further advice.*	*ISO 18113-X*	*IFU Ref: XXX*
	(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.		*Advice is present in the IFU for the users of self-testing devices to only adapt the treatment of a previously diagnosed condition if they have the training to do so.*	*ISO 18113-X*	*IFU Ref: XXX*

Looking for support?

Trinzo can support you in the compilation of your GSPR checklist by:

- Performing a gap analysis of your existing IVDD essential requirements to identify any remediation that must be completed to comply with the GSPRs • Assisting you in identifying which of the GSPRs are applicable to your device
- Auditing your GSPR checklist in advance of your notified body audit, to identify any potential future findings
- Remediating your risk management files, performance documentation, and labeling material to bring you into compliance with the GSPRs.

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Contact Us :

+353 (0) 91 394 804

www.trinzo.com
info@trinzo.com

Level One, Liosbán Business Park,
Tuam Road, Co. Galway, Ireland