TRINZO

EU MDR
GSPR Checklist



Under the Medical Device Regulation, the General Safety and Performance Requirements (GSPRs) of Annex I are more demanding that their Medical Device Directive counterparts, the Essential Requirements. Where the Directive included 13 Essential Requirements, the Regulation has 23 requirements that must be considered.

Medical device 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 – 9) examines the General Requirements related to risk management, risk control, and benefit-risk. The first eight GSPRs in this chapter apply to all devices.

Chapter II (GSPRs 10 – 22) deals with Requirements Regarding Design, and Manufacture. This chapter is broken down into the following subsections:

- Chemical, physical and biological properties
- Infection and microbial contamination
- Devices incorporating a substance considered to be a medical product
- Devices incorporating materials of biological origin
- Construction of devices and interaction with their environment
- Devices with a diagnostic or measuring function
- Protection against radiation
- Electronic programmable systems
- Active devices and devices connected to them
- Particular requirements for active implantable devices
- Protection against mechanical and thermal risks
- Protection against the risks posed to the patient or user by devices supplying energy or substances
- Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

Chapter III (GSPR 23) 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
- Information 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 1-9 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 update.

Suggested Standards		
Standard reference	**Title**	**Typically covers (non-exhaustive)**
EN 285:2015+A1	Sterilization – Steam sterilizers – Large sterilizers	Devices sterilised using steam
ISO 10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	Biocompatibility testing
ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	Biocompatibility testing
ISO 10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation	Biocompatibility testing
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 14160	Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	Sterilisation

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 15223-1	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 17664-1	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices	Medical device processing
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 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
IEC 60601-2-83	Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	Medical device equipment
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) MDR 2017/745 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 13485 Certificate* *Quality Manual* *Design and Development File* *Risk Management Procedure* *Ref: XXX* *RMF 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, benefit-risk ratio and risk acceptability; and (f) based on the evaluation of the impact	*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* *Usability Engineering File* *Ref: XXX* *RMF Ref: XXX* *Risk Management Procedure* *Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
	Chapter I – General Requirements				
	of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.				
4	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: (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.	*Y*	*The devices are manufactured to conform to safety principles through risk banalysis/assessment.* *The Risk Management procedure describes 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.*	*ISO 14971*	*Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IFU Ref: 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*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter I – General Requirements					
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*	*Risk Management Procedure Ref: XXX RMF 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 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*
8	All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved 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 13485 Certificate Risk Management Procedure Ref: XXX RMF Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter I – General Requirements					
9	For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons		*The Risk Management procedure describes the criteria for residual risk acceptability.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX*

Chapter II – Requirements Regarding Design and Manufacture					
GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
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:				
	(a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;		*The materials and substances used in the manufacture of this device are assessed as part of biocompatibility and risk assessment activities and are found to be acceptable.*	*ISO 13485* *ISO 14971* *ISO 10993-1*	*ISO 13485 Certificate* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Biocompatibility report Ref: XXX*
	(b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;		*The compatibility of the materials and substances of the device with biological tissue is examined as part of the biocompatibility testing and risk assessment activities and is found to be acceptable.*	*ISO 13485* *ISO 14971* *ISO 10993-1*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File* *Biocompatibility report Ref: XXX*
	(c) the compatibility between the different parts of a device which consists of more than one implantable part;		*The device is designed to ensure compatibility between all different parts of the device.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Risk Management ProcedureRef: XXX* *RMF Ref: XXX* *Design and Development File*
	(d) the impact of processes on material properties;		*This is examined as part of the device risk assessment and no significant impacts were identified*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File*
	(e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;		*Valid biophysical / modelling research (DELETE/RETAIN AS APPROPRIATE) results are acceptable.*	*ISO 13485* *ISO 14971* *ISO 10993-1*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File* *Biocompatibility report Ref: XXX*
	(f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;		*This is examined as part of the device risk assessment and no significant impacts were identified*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX*

Chapter II – Requirements Regarding Design and Manufacture					
GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
					RMF Ref: XXX *Design and Development File*
	(g) surface properties; and		*This is examined as part of the device risk assessment and no significant impacts were identified*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File*
	(h) the confirmation that the device meets any defined chemical and/or physical specifications.		*Physical specifications are documented in the device drawings. Chemical specifications are defined by the component materials.*	*ISO 13485* *ISO 14971* *ISO 10993-1*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File* *Biocompatibility report Ref: XXX*
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.		*Biocompatibility testing has concluded that the device is biologically safe for its intended use.* *Risk assessment activities concludes that biocompatibility risks are acceptable.*	*ISO 13485* *ISO 14971* *ISO 10993-1*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development FileBiocompatibility report Ref: XXX*
10.3	Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.		*The device is designed and manufactured to ensure compatibility with any substances that come into contact during normal use.* *Validation testing has confirmed that the device is compatible with the associated medicinal product (COMBINATION DEVICES ONLY).*	*ISO 13485* *ISO 14971* *ISO 10993-1*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File* *Validation report Ref: XXX*
10.4	Substances				
10.4.1	**Design and manufacture of Devices** Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and		*Risks posed by substances or particles, including wear debris, degradation products and processing residues considered during risk assessment*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX*

Chapter II – Requirements Regarding Design and Manufacture					
GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
	processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that: — are invasive and come into direct contact with the human body, — (re)administer medicines, body liquids or other substances, including gases, to/from the body, or — transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2: (a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5 of Regulation (EU) No 528/2012 of the European Parliament and the Council, in accordance with the criteria that are relevant to human health amongst the criteria established therein.		*activities. Risk controls by safe design and manufacture implemented to reduce risk as far as possible.* *CMR and endocrine-disrupting substances are not identified as a risk for this device.*		
10.4.2	**Justification regarding the presence of CMR and/or endocrine-disrupting substances** The justification for the presence of such substances shall be based upon: (a) an analysis and estimation of potential patient or user exposure to the substance; (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives; (c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and		*CMR and endocrine-disrupting substances are not identified as a risk for this device.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File*

Chapter II – Requirements Regarding Design and Manufacture					
GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
	(d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.				
10.4.3	**Guidelines on phthalates** For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.		*The use of phthalates in this device is examined as part of the risk assessment activities and the resulting benefit-risk analysis is found to be acceptable.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File*
10.4.4	**Guidelines on other CMR and endocrine disrupting substances.** Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.		*The use of CMR and endocrine disrupting substances in this device is examined as part of the risk assessment activities and the resulting benefit-risk analysis is found to be acceptable.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File*
10.4.5	**Labelling** Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for us.		*A reference to the presence of XXX substance is displayed on the device label. Precautionary information is provided in the IFU.*	*ISO 13485* *ISO 14971* *ISO 15223-1*	*ISO 13485 Certificate* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Design and Development File Label Ref: XXX* *IFU Ref: XXX*
10.5	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		*Contamination risks are examined as part of the device risk assessment and no significant risks were identified*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX*

Chapter II – Requirements Regarding Design and Manufacture					
GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
	to be used				*RMF Ref: XXX*
10.6	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.		*The device is designed and manufactured in such a way as to reduce as far as possible any risks related to the release of particles during use. These risks are examined as part of the risk assessment and biocompatibility testing and are found to be acceptable.*	*ISO 13485* *ISO 14971* *ISO 10993-1*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *Biocompatibility report 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 to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: (a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries, (b) allow easy and safe handling, (c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and (d) prevent microbial contamination of the device or its content such as specimens or fluids.		*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 15223-1*	*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	Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re sterilisation.		*The device is designed to allow for safe cleaning / disinfection / re sterilisation (DELETE AS APPROPRIATE)*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
11.3	Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.		*The device is designed, manufactured and packaged in such a way that the microbial state of the device remains during transport and storage and when it is placed on the market.*	*ISO 14937* *ISO 11135* *ISO 11137-1* *ISO 11737-2* *ISO 25424* *ISO 11737-1* *ISO 17665* *ISTA 2A* *ISO 15223-1*	*Design and Development FileSterility Verification and Validation Report* *Packaging Process XXX* *Manufacturing Instructions: XXX* *Transport Stability Report Ref: XXX* *Label Ref: XXX*
11.4	Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to		*This sterility of this device is maintained and confirmed throughout transport and storage, as recorded in the design and development file, sterility report,*	*ISO 14937* *ISO 11135* *ISO 11137-1* *ISO 11737-2*	*Design and Development FileSterility Verification and Validation Report* *Packaging Process XXX* *Manufacturing Instructions: XXX*

Chapter II – Requirements Regarding Design and Manufacture					
GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
	maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.		*and transport stability report.*	*ISO 25424* *ISO 11737-1* *ISO 17665* *ISTA 2A* *ISO 15223-1*	*Transport Stability Report Ref: XXX* *Label Ref: XXX*
11.5	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 15223-1*	*Design and Development FileSterility Verification and Validation Report* *Manufacturing Instructions: XXX* *Packaging Process XXX* *Cleanroom validation* *Label Ref: XXX*
11.6	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*
11.7	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*
11.8	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 15223*	*Sterile Device Label Ref: XXXNon-sterile Device Label Ref: XXX*
12	Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body				
12.1	In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal		*The quality, safety and usefulness of the medicinal product incorporated in this device is verified according to the*	*Directive 2001/83/EC* *ISO 13485*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk*

Chapter II – Requirements Regarding Design and Manufacture					
GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
	product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation.		*methods as specified in Annex I of Directive 2001/83/EC.*	*ISO 14971*	*Management Procedure Ref: XXX* *RMF Ref: XXX* *Validation and Verification report Ref: XXX*
12.2	Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.		*The substances incorporated in this device that are intended to be introduced into the human body are tested according to the methods as specified in Annex I of Directive 2001/83/EC.*	*Directive 2001/83/EC* *ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Validation and Verification report Ref: XXX*
13	Devices incorporating materials of biological origin				
13.1	For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: (a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC; (b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process; (c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.		*This device contains material of human (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*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Manufacturing Instructions: XXX* *Verification and Validation Report*
13.2	For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non viable or rendered non-viable the following shall apply: (a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall		*This device contains material of animal (XXX) origin.* *A certificate of origin is available. The supplier is qualified and on the critical supplier list.*	*ISO 13485* *ISO 14971* *Regulation (EU) No 722-2012*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX*

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	originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers; (b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device; (c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.				*Manufacturing Instructions: XXX* *Verification and Validation Report*
13.3	For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing,preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.		*This device contains non-viable biological substances (XXX).* *A certificate of origin is available. The supplier is qualified and on the critical supplier list.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Manufacturing Instructions: XXX* *Verification and Validation Report*
14	Construction of devices and interaction with their environment				
14.1	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 performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.		*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 15223* *ISO 14971* *ISO 62366*	*Design and Development FileVerification and Validation Report Label Ref: XXX* *IFU Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF File Ref: XXX* *Usability Engineering File Ref: XXX*
14.2	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:				

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	(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 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 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 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 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *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 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 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *Verification and Validation Report*
	(f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and		*Risks of reciprocal interference with other devices are assessed as part of the risk management activities and 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* *Verification and Validation Report*

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	(g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.		*Risks related to the inability to perform maintenance and calibration are assessed as part of the risk management activities and 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* *Verification and Validation Report*
14.3	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.		*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 Procedure Ref: XXX* *RMF Ref: XXX* *IFU/Manual Ref: XXX* *Label Ref: XXX*
14.4	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*
14.5	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*
14.6	Any measurement, monitoring or display scale 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*
14.7	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 the user, patient 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* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File IFU Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX*

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15	Devices with a diagnostic or measuring function				
15.1	Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.		*The measurement requirements for this device are outlined the Design and Development File, and performance is verified. Limits of accuracy are communicated in the IFU.*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File IFU Ref: XXX*
15.2	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*
16	Protection against radiation				
16.1	**General** (a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation 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 therapeutic and diagnostic purposes. (b) 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 patient and 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 is designed and manufactured in such a way that radiation exposure reduced as far as possible without affecting the performance of the device.* *The IFU contains information on the emitted radiation and the means of user protection.* *Risks associated with radiation are examined as part of risk assessment activities and are found to be acceptable.*	*ISO 13485* *ISO 14971* *ISO 15223-1*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IFU Ref: XXX*
16.2	**Intended radiation** (a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or nonionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. (b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non ionizing radiation,		*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* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Verification and Validation Report Risk Management Procedure* *Ref: XXX* *RMF Ref: XXX*

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	they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.				
16.3	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.		*The device is designed and manufactured in such a way that the exposure to radiation is reduced as far as possible. Exposure to radiation is examined as part of the risk assessment activities and was 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*
16.4	**Ionising radiation** (a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. (b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment. (c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user. (d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.		*This device is designed ad manufactured in such a way as to take into account th e requirements of the Euratom Directive. As a device that is intended to emit ionising radiation, it is designed and manufactured in such as way as to ensure that the emitted radiation can be varied, controlled and monitored. Radiation levels are limited to the lowest possible level required to achieve the intended purpose of the device.*	*Directive 2013/59/EuratomI* *SO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure* *Ref: XXX* *RMF Ref: XXX*
17	Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves				
17.1	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.*	*ISO 13485* *ISO 62304*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Verification and Validation Report*
17.2	For devices that incorporate software or for software that are		*The device software is developed*	*ISO 13485*	*ISO 13485 Certificate*

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	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.		*and manufactured in accordance with SOTA and with the principles of development life cycle, risk management, and verification and validation in mind.*	*ISO 14971* *ISO 62304*	*Quality Manual* *Design and Development File* *Manufacturing Instructions: XXX* *Verification and Validation Report* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *CER Ref: XXX*
17.3	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 13485 Certificate* *Quality Manual* *Design and Development File* *Manufacturing Instructions: XXX* *Verification and Validation Report CER Ref: XXX* *IFU / Manual Ref: XXX*
17.4	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 15223-1* *ISO 14971*	*IFU / Manual Ref: XXX* *Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
18	Active devices and devices connected to them				
18.1	For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.		*Risks related to a single fault condition are eliminated / reduced as far as possible (DELETE AS APROPRIATE).*	*ISO 60601* *ISO 14971*	*Design and Development FileRisk Management Procedure Ref: XXX* *RMF Ref: XXX*
18.2	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.		*An alarm is present on the device to indicate when the power supply is low before the supply level becomes critical.*	*ISO 60601* *ISO 14971*	*Design and Development FileRisk Management Procedure Ref: XXX* *RMF Ref: XXX*
18.3	Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.		*An alarm is present on the device to signal a power failure.*	*ISO 60601* *ISO 14971*	*Design and Development FileRisk Management Procedure Ref: XXX* *RMF Ref: XXX*
18.4	Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.		*An alarm is present on the device to alert users to situations leading to the death or serious deterioration of the health of the patient.*	*ISO 60601* *ISO 14971*	*Design and Development FileRisk Management Procedure Ref: XXX* *RMF Ref: XXX*

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18.5	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.		*The device is designed and manufactured in such a way that EMI is reduced as far as possible.*	*ISO 60601* *ISO 14971*	*Design and Development FileRisk Management Procedure Ref: XXX* *RMF Ref: XXX*
18.6	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.		*The device is designed and manufactured in such a way that there is sufficient immunity to EMI to allow for normal operation.*	*ISO 60601* *ISO 14971*	*Design and Development FileRisk Management Procedure Ref: XXX* *RMF Ref: XXX*
18.7	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 patient, user or any 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.		*The device is designed and manufactured in such a way that risks of accidental shocks are avoided as far as possible. This risk is also examined as part of the risk assessment and found to be acceptable.*	*ISO 60601* *ISO 14971*	*Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
18.8	Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.		*The device is designed and manufactured in such a way that unauthorised access is protected against as far as possible.*	*ISO 60601* *ISO 14971*	*Design and Development FileRisk Management Procedure Ref: XXX* *RMF Ref: XXX*
19	Particular requirements for active implantable devices				
19.1	Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible: (a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices, (b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high frequency surgical equipment, and (c) risks which may arise where maintenance and calibration are impossible, including: — excessive increase of leakage currents, — ageing of the materials used, — excess heat generated by the device, — decreased accuracy of any measuring or control mechanism.		*The device is designed and manufactured to reduce as far as possible the risks associated with the energy source, medical treatment, and maintenance and calibration (DELETE AS APPROPRIATE)*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
19.2	Active implantable devices shall be designed and manufactured in such a way as to ensure - if applicable, the compatibility of the devices with the substances they are intended to administer, and		*The device is designed and manufactured to ensure compatibility with associated substances, and the reliability of*	*ISO 13485*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File*

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	- the reliability of the source of energy.		*the energy source.*		
19.3	Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.		*The device and its parts are identifiable to allow for measures to be taken in the event of an identified risk..*	*ISO 13485* *ISO 14971*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure Ref: XXX* *RMF Ref: XXX*
19.4	Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.		*A code is present on the device, providing information on the device type and it's year of manufacture. It is possible to read the code without surgical intervention (PROVIDE DETAIL)*	*ISO 13485*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File*
20	Protection against mechanical and thermal risks				
20.1	Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.		*The potential for mechanical risks is assessed as part of the risk management activities and is found to be acceptable.*	*ISO 13485* *ISO 14971* *ISO 60601*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure* *Ref: XXX* *RMF Ref: XXX*
20.2	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* *ISO 60601*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure* *Ref: XXX* *RMF Ref: XXX*
20.3	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 areassessed as part of the risk management activities and are found to be acceptable.*	*ISO 13485* *ISO 14971* *ISO 60601*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure* *Ref: XXX* *RMF Ref: XXX*
20.4	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* *ISO 60601*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File Risk Management Procedure* *Ref: XXX* *RMF Ref: XXX*

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20.5	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 information on the parts.*	*ISO 13485 ISO 14971 ISO 60601 ISO 62366*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX Label Ref: XXX IFU / Manual Ref: XXX Usability Engineering File Ref: XXX*
20.6	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.*	*ISO 14971 ISO 60601*	*IEC Report Ref: XXX Verification/Verification and Validation Report Risk Management Procedure Ref: XXX RMF Ref: XXX*
21	Protection against risks posed to the patient or users by devices supplying energy or substances				
21.1	Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.		*The device is designed and manufactured in such a way that the amount of energy / substance (DELETE AS APPROPRIATE) supplied to the patient is set and accurately maintained to ensure patient / user (DELETE AS APPROPRIATE) safety.*	*ISO 13485 ISO 14971 ISO 60601*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX*
21.2	Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.		*The device is fitted with XXX, which indicates to the user / prevents any inadequacies in the amount of energy or substances delivered. The accidental release of dangerous levels of energy or substances is prevented as far as possible by XXX.*	*ISO 13485 ISO 14971 ISO 60601*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX*
21.3	The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.		*The function of the controls and indicators are specified on the device. 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 60601*	*ISO 13485 Certificate Quality Manual Design and Development File Risk Management Procedure Ref: XXX RMF Ref: XXX IFU Ref: XXX*

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22	Protection against the risks posed by medical devices intended for use by laypersons.				
22.1	Devices for use by lay persons 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 lay persons and the influence resulting from variation that can be reasonably anticipated in the layperson's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.		*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* *IEC 62366* *ISO 15223-1*	*ISO 13485 Certificate* *Quality Manual* *Design and Development File* *Usability Engineering File Ref: XXX* *IFU Ref: XXX*
22.2	Devices for use by lay persons shall be designed and manufactured in such a way as to: - ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information, - reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and - reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.		*Usability testing has confirmed that the 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* *ISO 14971* *ISO 15223-1*	*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*
22.3	Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person: - can verify that, at the time of use, the device will perform as intended by the manufacturer, and - if applicable, is 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 13485* *ISO 14971* *IEC 62366*	*Risk Management Procedure Ref: XXX* *RMF Ref: XXX* *IFU / Manual Ref: XXX* *Usability Engineering File Ref: XXX* *IFU Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter III – Requirements Regarding Information Supplied With The Device					
23	Label and instructions for use				
23.1	**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 13485* *ISO 14971* *ISO 15223-1*	*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, and/or on the packaging of multiple devices.		*The information that is provided on the device label is also provided on the device itself.*	*ISO 13485* *ISO 14971* *ISO 15223-1*	*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 ('RFID') or bar codes.		*Labels are provided in human readable format.*	*ISO 13485* *ISO 14971* *ISO 15223-1*	*Label Ref: XXX*
	(d) Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.		*Instructions for use are provided with the device.*	*ISO 13485* *ISO 14971* *ISO 15223-1*	*IFU Ref: XXX*
	(e) Where multiple devices 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 13485* *ISO 14971* *ISO 15223-1*	*IFU Ref: XXX*
	(f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.		*The IFU is provided in electronic format OR* *The IFU is provided in paper format.*	*ISO 13485* *ISO 14971* *ISO 15223-1*	*IFU Ref: XXX*
	(g) Residual risks which are required to be communicated to		*Residual risks are communicated in the*	*ISO 13485*	*Risk Management Procedure*

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	the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.		*IFU.*	*ISO 14971* *ISO 15223-1*	*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. 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 13485* *ISO 14971* *ISO 15223-1*	*IFU Ref: XXX* *Label Ref: XXX*
	Information on the label The label shall bear all of the following particulars:				
23.2	(a) the name or trade name of the device;				
	(b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious or the user, the intended purpose of the device;		*The intended purpose of the device is present on the label.*	*ISO 15223-1*	*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 15223-1*	*Label Ref: XXX*
	(d) if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and 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 15223-1*	*Label Ref: XXX*
	(e) where applicable, an indication that the device contains or incorporates: — a medicinal substance, including a human blood or plasma derivative, or — tissues or cells, or their derivatives, of human origin, or tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;		*An indication that this device contains XXX is present on the label*	*ISO 15223-1*	*Label Ref: XXX*
	(f) where applicable, information labelled in accordance with Section 10.4.5.;		*Information on CMR and endocrine disrupting substances are included on the device label.*	*ISO 15223-1*	*Label Ref: XXX*

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	(g) 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 15223-1*	*Label Ref: XXX*
	(h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII;		*The UDI carrier is present on the device label.*	*ISO 15223-1*	*Label Ref: XXX*
	(i) an unambiguous indication of the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;		*The expiration date of the device is present on the device label.*	*ISO 15223-1*	*Label Ref: XXX*
	(j) 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 15223-1*	*Label Ref: XXX*
	(k) an indication of any special storage and/or handling condition that applies;		*Storage conditions are present on the device label.*	*ISO 15223-1*	*Label Ref: XXX*
	(l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method;		*There is an indication present on the label to identify the device as sterile including the appropriate symbol to identify the sterilisation method.*	*ISO 15223-1*	*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, and 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 15223-1*	*Label Ref: XXX*
	(n) 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 15223-1*	*Label Ref: XXX*
	(o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;		*The labelling identifies the device as being a reprocessed single-use device and includes information on the number of reprocessing cycles performed and the limitation on reprocessing cycles.*	*ISO 15223-1*	*Label Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
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	(p) if the device is custom-made, the words 'custom made device';		*The words 'custom-made device' are present on the device label.*	*ISO 15223-1*	*Label Ref: XXX*
	(q) an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation';		*The words 'exclusively for clinical investigations' are present on the device label.*	*ISO 15223-1*	*Label Ref: XXX*
	(r) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action;		*The overall qualitative composition of the device and of the main constituent (XXX) is present on the device label.*	*ISO 15223-1*	*Label Ref: XXX*
	(s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number		*The serial number OR the lot number is present on the device label*	*ISO 15223-1*	*Label Ref: XXX*
23.3	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 15223-1*	*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 15223-1*	*Label Ref: XXX*
	(c) the method of sterilisation,		*The method of sterilisation is referenced on the device packaging.*	*ISO 15223-1*	*Label Ref: XXX*
	(d) the name and address of the manufacturer,		*The name and address of the manufacturer is referenced on the packaging.*	*ISO 15223-1*	*Label Ref: XXX*
	(e) a description of the device,		*A description of the device is present on the packaging.*	*ISO 15223-1*	*Label Ref: XXX*
	(f) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations',		*The words 'exclusively for clinical investigations' are present on the device packaging*	*ISO 15223-1*	*Label Ref: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter III – Requirements Regarding Information Supplied With The Device					
	(g) if the device is custom-made, the words 'custom made device',		*The words 'custom-made device' are present on the device packaging*	*ISO 15223-1*	*Label Ref: XXX*
	(h) the month and year of manufacture,		*The month and year of manufacture is referenced on the packaging.*	*ISO 15223-1*	*Label Ref: XXX*
	(i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and		*The confirmed stability of the device is referenced on the packaging in YYYY MM-DD.*	*ISO 15223-1*	*Label Ref: XXX*
	(j) 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 15223-1*	*Label Ref: XXX*
23.4	Information in the instructions for use The instructions for use shall contain all of the following particulars:				
	(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2;		*The IFU contains all of the elements as referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX*
	(b) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;		*The intended purpose of the device is present in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(c) where applicable, a specification of the clinical benefits to be expected.		*A specification of the expected clinical benefits is present in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(d) where applicable, links to the summary of safety and clinical performance referred to in Article 32;		*A link to the SSCP is present in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(e) the performance characteristics of the device;		*The performance characteristics of the device are present in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;		*Information is provided for the user to verify that the device is suitable for their requirements, and for the selection of software and accessories.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
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	(g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;		*Residual risks, contraindications and side effects are communicated in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(h) specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it;		*Specifications for appropriate use are provided in the IFU*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(i) details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;		*Details on the required preparations are provided in the IFU (PROVIDE DETAIL)*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;		*Requirements for special facilities / special training / user qualifications (DELETE OR RETAIN AS APPROPRIATE) are included in the IFU*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(k) 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, and of any preparatory cleaning or 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, and — methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;		*Information on the verification of proper installation and performance safety are provided in the IFU, including maintenance, consumables, calibration and installation, calibration and services risks (DELETE OR RETAIN AS APPROPRIATE)*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;		*The sterile nature of the device and instructions to be followed in the event of damage to the sterile packaging before use are all referenced in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;		*An indication that the device should be sterilised before use is present in the IFU, along with the instructions for sterilisation.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
	Chapter III – Requirements Regarding Information Supplied With The Device				
	(n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;		*Information is provided on the required reuse preparation is provided in the IFU, along with an indication of limitations on the number of reuses.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;		*An indication that the device can only be reused if it is reconditioned by the manufacturer is present in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(p) if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request;		*Risks related to the reuse of this single use device were examined as part of the risk assessment and information related to these risks is provided in the IFU.*	*ISO 13485* *ISO 15223-1* *ISO 14971*	*IFU Ref: XXX; Section: XXXRisk Management Procedure Ref: XXX* *RMF Ref: XXX*
	(q) for devices intended for use together with other devices and/or general purpose equipment: — information to identify such devices or equipment, in order to obtain a safe combination, 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 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(r) if the device emits radiation for medical purposes: — detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation, — the means of protecting the patient, user, or other person from unintended radiation during use of the device;		*Information on the nature of the radiation that is emitted by this device is provided in the IFU, along with details on the appropriate protection of users and patients during device use.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(s) information that allows the user and/or patient to be informed of any warnings, precautions, contraindications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use		*Information related tolimitations, warnings, precautions and contradictions are provided in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
	Chapter III – Requirements Regarding Information Supplied With The Device				
	regarding the device. The information shall cover, where appropriate: — warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety, — warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, — warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, — if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered, — warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and — 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;				
	(t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side-effects and risks relating to overdose;		*Information is provided in the IFU on warnings and precautions, contraindications, side effects and risks related to substances making up this device.*	*ISO 13485* *ISO 15223-1* *ISO 14971*	*IFU Ref: XXX; Section: XXXRisk Management Procedure Ref: XXX* *RMF Ref: XXX*
	(u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;		*The qualitative and quantitative information on the substances to which patients are exposed are*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*

GSPR	Description	Applicable Y/N	Methods Applied	Standards and Solutions	Evidence
Chapter III – Requirements Regarding Information Supplied With The Device					
			included in the IFU		
	(v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate: — infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and — physical hazards such as from sharps. If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;		*Information is provided in the IFU on safe device disposal including references to infection/microbial, environmental, and physical hazards.*	*ISO 13485* *ISO 15223-1* *Directive 2012/19/EU (WEEE)* *Directive 2011/65/EU (RoHS)*	*IFU Ref: XXX; Section: XXX*
	(w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;		*As a device intended for laypersons, information is provided in the IFU on the circumstances in which a professional should be consulted*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;		*This device does not have an intended medical purpose; information related to the absence of a clinical benefit and the risks related to the device use are present in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(y) 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;		*The date of issue and revision number are present in the IFU*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX*
	(z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or 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 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*

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Chapter III – Requirements Regarding Information Supplied With The Device					
	(aa) information to be supplied to the patient with an implanted device in accordance with Article 18;		*The information as required by Article 18 is present in the IFU.*	*ISO 13485* *ISO 15223-1*	*IFU Ref: XXX; Section: XXX*
	(ab) 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 13485* *ISO 15223-1* *ISO 62304*	*IFU Ref: XXX; Section: XXX*

Looking for support on your MDR Journey?

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

- 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 labelling material to bring you into compliance with the GSPRs

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