Checklist: MDR General Safety and Performance Requirements

Chapter I: General Requirements

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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	Yes		ISO 14971:2019	Intended UseRisk Management ReportClinical Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	Yes		ISO 14971:2019	Risk Management Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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:	Yes		ISO 14971:2019	SOP Integrated Software Development

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	establish and document a risk management plan for each device;	Yes		ISO 14971:2019	Risk Management Plan
(b)	identify and analyze the known and foreseeable hazards associated with each device;	Yes		ISO 14971:2019	Risk Table
(c)	estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;	Yes		ISO 14971:2019	Risk Table

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(d)	eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;	Yes		ISO 14971:2019	Risk Table

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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	Yes		ISO 14971:2019	Risk TableSOP Integrated Software Development

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(f)	based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.	Yes		ISO 14971:2019	Risk Table

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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	Yes		ISO 14971:2019	Risk Table

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	eliminate or reduce risks as far as possible through safe design and manufacture;	Yes		ISO 14971:2019	Risk Table
(b)	where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and	Yes		ISO 14971:2019	Risk Table
(c)	provide information for safety (warnings/precautions/contraindications) and, where appropriate, training to users.	Yes		ISO 14971:2019	Risk Table

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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	Yes		IEC 62366-1:2015 + COR1:2016	Risk TableSoftware Requirements ListUsability Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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).	Yes		IEC 62366-1:2015 + COR1:2016	Intended UseRisk Table

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
8	All known and foreseeable risks, and any undesirable side-effects, shall be minimized 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.	Yes		ISO 14971:2019	Clinical Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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	No	Annex XVI does not apply		

Chapter II: Requirements Regarding Design and Manufacture

2.1) Chemical, Physical and Biological Properties

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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:	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(c)	the compatibility between the different parts of a device which consists of more than one implantable part;	No	Software device		
(d)	the impact of processes on material properties;	No	Software device		
(e)	where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(f)	the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;	No	Software device		
(g)	surface properties; and	No	Software device		
(h)	the confirmation that the device meets any defined chemical and/or physical specifications.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
10.2	Devices shall be designed, manufactured and packaged in such a way as to minimize 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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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	No	Software device		

2.2) Substances

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
10.4.1	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 processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that:	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— are invasive and come into direct contact with the human body,	No	Software device		
	— (re)administer medicines, body liquids or other substances, including gases, to/from the body, or	No	Software device		
	— transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	shall only contain the following sub-stances in a concen-tration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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 (1), or	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects on 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 (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
10.4.2	Justification regarding the presence of CMR and/or endocrine-disrupting sub-stances: The justi-fication for the presence of such sub-stances shall be based upon:	No	Software device		
(a)	an analysis and esti-mation of potential patient or user exposure to the sub-stance;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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 breast-feeding women or treatment of other patient groups consid-	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(d)	where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
10.4.4	Guidelines on other CMR and endocrine-disrupting sub-stances:Subsequently, the Com-mission shall mandate the relevant scientific commit-tee to prepare guide-lines as referred to in Section 10.4.3. also for other sub-stances referred to in points (a) and (b) of Section 10.4.1., where appropri-ate.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
10.4.5	Labelling: Where devices, parts thereof or materials are 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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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 to be used.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

2.3) Infection and Microbiological Contamination

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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:	No	Software device		
(a)	reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	allow easy and safe handling,	No	Software device		
(c)	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and	No	Software device		
(d)	prevent microbial contamination of the device or its content such as specimens or fluids.	No	Software device		
11.2	Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilization.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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 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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
11.5	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilized by means of appropriate, validated methods.	No	Software device		
11.6	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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 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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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,	No	Software device		

2.4) Devices Incorporating Materials of Biological Origin

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
13.1	For devices manufactured utilizing 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:	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
13.2	For devices manufactured utilizing tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall 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;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(c)	in the case of devices manufactured utilizing 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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
13.3	For devices manufactured utilizing 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	No	Software device		

2.5) Construction of Devices and Interaction with their Environment

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity

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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
14.2	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:	No	Software device		
(a)	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	Yes	Software device	IEC 62366-1:2015 + COR1:2016	Risk TableUsability Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	Software device		
(d)	the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;	Yes	ISO 14971:2919		Risk Table

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(e)	the risks of accidental ingress of substances into the device;	No	Software device		
(f)	the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
14.3	Devices shall be designed and manufactured in such a way as to minimize 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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
14.4	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	Yes		IEC 62304:2006 / AMD1:2015	Software Development and Maintenance Plan
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.	Yes		IEC 62304:2006 / AMD1:2015	Software Requirements List

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	No measuring function		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

2.6) Devices with a Diagnostic or Measurement Function

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	No measuring function		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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 (4).	No	No measuring function		

2.7) Protection Against Radiation

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
16.1	General				

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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.	No	No radiation		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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 accep-	No	No radiation		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
16.2	Intended radiation				

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing 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	No	No radiation		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.	No	No radiation		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	No radiation		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
16.4	Ionizing 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 ionizing radiation.	No	No radiation		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	Devices intended to emit ionizing 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.	No	No radiation		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(c)	Devices emitting ionizing 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 minimizing radiation exposure of the patient and user.	No	No radiation		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(d)	Devices that emit ionizing 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.	No	No radiation		

2.8) Devices that Incorporate Electronic Programmable Systems and Softwares that are Devices Themselves

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
No.	**Requirement**	**Applicable**	**Rationale**	**Applicable Standard**	**Evidence of Conformity**
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.	Yes		IEC 62304:2006 / AMD1:2015	Intended UseSOP Integrated Software DevelopmentSOP Change Management

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
17.2	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.	Yes		IEC 62304:2006 / AMD1:2015	Software Development and Maintenance PlanClinical Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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).	Yes		IEC 62304:2006 / AMD1:2015	SOP Integrated Software DevelopmentSoftware Requirements List

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
17.4	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.	Yes		IEC 62304:2006 / AMD1:2015	User ManualSoftware Requirements List

2.9) Active Devices and Devices Connected to Them

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	Yes		ISO 14971:2019	Risk Table

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Safety does not depend on power supply		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Safety does not depend on power supply		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	No monitoring of clinical parameters		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
18.8	Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorized access that could hamper the device from functioning as intended.	Yes		ISO 14971:2019	Technical and Organizational MeasuresSoftware Requirements List

2.10) Particular requirements for active implantable devices

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
19.1	Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:	No	Software device		
(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,	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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 reliability of the source of energy.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

2.11) Protection Against Mechanical and Thermal Risks

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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 risk.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

2.12) Protection against the risks posed to the patient or user by devices supplying energy or substances

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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.	No	Software device		

2.13) Protection against the risks by medical devices intended by manufacturers for use by lay persons

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
No.	**Requirement**	**Applicable**	**Rationale**	**Applicable Standard**	**Evidence of Conformity**
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 lay person's technique and environment. The information and instructions provided by the manufacturer shall be	Yes		IEC 62366-1:2015 + AC:2015	Intended UseUser ManualUsability Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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,	Yes		IEC 62366-1:2015 + AC:2015	Usability Evaluation Report(Record of User Training)

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and	No	Software device		
	— 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.	Yes		IEC 62366-1:2015 + AC:2015	Usability Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
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	Yes		IEC 62366-1:2015 + AC:2015	Stakeholder RequirementsUsability Evaluation Report
	— if applicable, is warned if the device has failed to provide a valid result.	Yes		IEC 62366-1:2015 + AC:2015	Stakeholder RequirementsUsability Evaluation Report

Chapter III: Requirements Regarding the Information Supplied with the Device

3.1) Label and Instructions for Use

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
23.1	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				

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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.	Yes		IEC 62304:2006 / AMD1:2015	Software Requirements ListSOP Certification and Product Registration

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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.	Yes		IEC 62304:2006 / AMD1:2015	Software Requirements ListSOP Certification and Product Registration

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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.	Yes		IEC 62304:2006 / AMD1:2015,IEC 62366-1:2015 + AC:2015	User Manual, Software Requirements List

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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.	Yes			

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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.	Yes		IEC 62304:2006 / AMD1:2015,IEC 62366-1:2015 + AC:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.	Yes		IEC 62304:2006 / AMD1:2015,IEC 62366-1:2015 + AC:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(h)	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized 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.	Yes		ISO 15223-1:2017	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
23.2	The label shall bear all of the following particulars:				
(a)	the name or trade name of the device;	Yes			User Manual
(b)	the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;	Yes			User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(c)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;	Yes			User Manual
(d)	if the manufacturer has its registered place of business outside the Union, the name of the authorized representative and address of the registered place of business of the authorized representative;	No	Based in EU		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(f)	where applicable, information labelled in accordance with Section 10.4.5.;	No	Section is not applicable		
(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;	No	No batch production		
(h)	the UDI carrier referred to in Article 27(4) and Part C of Annex VII;	Yes		IEC 62304:2006 / AMD1:2015,IEC 62366-1:2015 + AC:2015	User ManualSOP Certification and Product Registration

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	Yes			
(k)	an indication of any special storage and/or handling condition that applies;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(l)	if the device is supplied sterile, an indication of its sterile state and the sterilisation method;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	Not necessary based on risk file		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	No single use device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	No single use device		
(p)	if the device is custom-made, the words 'custom-made device';	No	Not custom-made		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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';	Yes			

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(s)	for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.	No	Software device		
23.3	For packaging which maintains the sterile condition of a device ('sterile packaging'), the following particulars shall appear on the sterile packaging:				

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	an indication permitting the sterile packaging to be recognized as such,	No	Software device		
(b)	a declaration that the device is in a sterile condition,	No	Software device		
(c)	the method of sterilization,	No	Software device		
(d)	the name and address of the manufacturer,	No	Software device		
(e)	a description of the device,	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(f)	if the device is intended for clinical investigations, the words 'exclusively for clinical investigations',	No	Software device		
(g)	if the device is custom-made, the words 'custom-made device',	No	Software device		
(h)	the month and year of manufacture,	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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	No	Software device		
(j)	an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
23.4	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;	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	Yes		IEC 62304:2006 / AMD1:2015	User Manual
(c)	where applicable, a specification of the clinical benefits to be expected.	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(d)	where applicable, links to the summary of safety and clinical performance referred to in Article 32;	No	Software device		
(e)	the performance characteristics of the device;	Yes		IEC 62304:2006 / AMD1:2015	User Manual
(f)	where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(g)	any residual risks, contra-indications and any undesir-able side-effects, including informa-tion to be conveyed to the patient in this regard;	Yes		IEC 62304:2006 / AMD1:2015	User Manual
(h)	specifications the user requires to use the device appropri-ately, e.g. if the device has a measur-ing function, the degree of accuracy claimed for it;	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(i)	details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilization, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(j)	any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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 calibra-	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(l)	if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;	No	Software device		
(m)	if the device is supplied non-sterile with the intention that it is sterilized before use, the appropriate instructions for sterilization;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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-sterilization 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 maxi-	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	No restrictions on reuse		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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	No	No single-use device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	Yes		IEC 62304:2006 / AMD1:2015	User Manual
(r)	if the device emits radiation for medical purposes:				

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation,	No	Software device		
	— the means of protecting the patient, user, or other person from unintended radiation during use of the device;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(s)	information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, 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 regarding the device. The information shall cover, where	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— 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,	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— 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,	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— 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,	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— 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,	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— 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	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— 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;	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(u)	in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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:	No	Not required based on risk file		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and	No	Software device		
	— physical hazards such as from sharps.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	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;	No	IFU exist		
(w)	for devices intended for use by lay persons, the circumstances in which the user should consult a health-care professional;	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	No	Clinical benefit exists		
(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;	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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;	Yes		IEC 62304:2006 / AMD1:2015	User Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(aa)	information to be supplied to the patient with an implanted device in accordance with Article 18;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(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 unauthorized access, necessary to run the software as intended.	Yes		IEC 62304:2006 / AMD1:2015	User Manual

Annex II: Technical Documentation

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

4.1.1) Device Description and Specification

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	product or trade name and a general description of the device including its intended purpose and intended users;	Yes		IEC 62304:2006 / AMD1:2015	Intended Use

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;	Yes		IEC 62304:2006 / AMD1:2015	UDI LabelSOP Certification and Product Registration

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(c)	the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;	Yes		IEC 62304:2006 / AMD1:2015	Intended Use
(d)	principles of operation of the device and its mode of action, scientifically demonstrated if necessary;	Yes		IEC 62304:2006 / AMD1:2015	Intended Use

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(e)	the rationale for the qualification of the product as a device;	Yes		IEC 62304:2006 / AMD1:2015	Medical Device Classification
(f)	the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;	Yes		IEC 62304:2006 / AMD1:2015	Medical Device Classification
(g)	an explanation of any novel features;	Yes		IEC 62304:2006 / AMD1:2015	Intended Use

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(h)	a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;	No	No device accessories		
(i)	a description or complete list of the various configurations/variants of the device that are intended to be made available on the market;	Yes		IEC 62304:2006 / AMD1:2015	Medical Devices List

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(j)	a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the	Yes		IEC 62304:2006 / AMD1:2015	Software Development and Maintenance PlanSoftware Requirements List

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(k)	a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(l)	technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.	Yes		IEC 62304:2006 / AMD1:2015	Software Requirements ListMarketing Material

4.1.2) References to Previous and Similar Generations of the Device

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;	Yes		ISO 13485:2016	Medical Devices List
(b)	an overview of identified similar devices available on the Union or international markets, where such devices exist.	Yes		ISO 13485:2016	Medical Devices ListClinical Evaluation Report

4.2) Information to be Supplied by the Manufacturer

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	A complete set of — the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; and	Yes		ISO 13485:2016,IEC 62304:2006 / AMD1:2015	UDI LabelUser Manual

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	— the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.	Yes		IEC 62304:2006 / AMD1:2015	User Manual

4.3) Design and Manufacturing Information

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	information to allow the design stages applied to the device to be understood;	Yes		IEC 62304:2006 / AMD1:2015	Software Development and Maintenance Plan

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;	Yes		ISO 13485:2016,IEC 62304:2006 / AMD1:2015	SOP Integrated Software DevelopmentSoftware Requirements ListSystem Test Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(c)	identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.	Yes		ISO 13485:2016,IEC 62304:2006 / AMD1:2015	Quality Management ManualList of Qualified Suppliers

4.4) General Safety and Performance Requirements

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity

	The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall	Yes			MDR General Safety and Performance Requirements Checklist

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;	Yes			MDR General Safety and Performance Requirements Checklist
(b)	the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;	Yes			MDR General Safety and Performance Requirements Checklist
(c)	the harmonized standards, CS or other solutions applied; and	Yes			MDR General Safety and Performance Requirements Checklist

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(d)	the precise identity of the controlled documents offering evidence of conformity with each harmonized standard, CS 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 within the full technical documentation and, if applicable, the summary technical	Yes			MDR General Safety and Performance Requirements Checklist

4.5) Benefit-Risk-Analysis and Risk Management

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	The documentation shall contain information on:				
(a)	the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and	Yes		ISO 13485:2016	Clinical Evaluation Report
(b)	the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.	Yes		ISO 13485:2016,ISO 14971:2019	Risk TableRisk Management Report

4.6) Product Verification and Validation

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

4.6.1) Pre-Clinical and Clinical Data

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(a)	results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the preclinical safety of the device and its conformity with the specifications;	Yes		ISO 13485:2016	Clinical Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:				
	— the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— physical, chemical and microbiological characterization;	No	Software device		
	— electrical safety and electromagnetic compatibility;	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different	Yes		IEC 62304:2006 / AMD1:2015	Software Requirements ListSystem Test ReportUsability Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— stability, including shelf life; and	No	Software device		
	— performance and safety.	Yes		ISO 13485:2016,ISO 14971:219,IEC 62304:2006 / AMD1:2015	Risk Management ReportClinical Evaluation Report

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council (1) shall be demonstrated. Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(c)	the clinical evaluation report and its updates and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV;	Yes		ISO 13485:2016	Clinical Evaluation PlanClinical Evaluation Report
(d)	the PMCF plan and PMCF evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable.	Yes		ISO 13485:2016	Post-Market Clinical Follow-Up Plan and Report

4.6.2) Additional Information Required in Specific Cases

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity

(a)	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8), a statement indicating this fact. In this case, the documen-	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(b)	Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6, and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(c)	In the case of devices that are composed of substances or 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, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— absorption, distribution, metabolism and excretion;	No	Software device		
	— possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions;	No	Software device		
	— local tolerance; and	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
	— toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device.	No	Software device		
	In the absence of such studies, a justification shall be provided.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(d)	In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I, the justification referred to in Section 10.4.2 of that Annex.	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(e)	In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilization and maintenance of sterility. The validation report shall address	No	Software device		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(f)	In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.	No	No measuring function		

No.	Requirement	Applicable	Rationale	Applicable Standard	Evidence of Conformity
(g)	If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.	No	Standalone software device		

Template Copyright openregulatory.com. See template license.

Please don't remove this notice even if you've modified contents of this template.