**Device Name:** **Classification:**

| **APPROX.**  **MDD**  **PARAG.**  **REF.** | **MDR REQUIREMENTS**  **Numbering per MDR** | **APPLICABLE?**  **(Yes / No)** | **RELEVANT STANDARD** | **COMPLIANCE ASSESSMENT REFERENCE** | **IDENTITY & LOCATION**  **OF SUPPORTING DOCUMENTS** |
| --- | --- | --- | --- | --- | --- |
| 1 | **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. | Yes | EN ISO 13485:2016  EN ISO 14971:2019 |  |  |
| 1 | **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 | EN ISO 14971:2019  EN ISO 13485:2016 |  |  |
| 1 | **3.**  Manufacturers shall establish, implement, document and maintain a risk management system. | Yes | EN ISO 14971:2019  EN ISO 13485:2016 |  |  |
| 1 | **3.**  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; | Yes | EN ISO 14971:2019  EN ISO 13485:2016 |  |  |
| 1 | (b) identify and analyse the known and foreseeable hazards associated with each device; | Yes | EN ISO 14971:2019  EN ISO 13485:2016 |  |  |
| 1 | (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; | Yes | EN ISO 14971:2019  EN ISO 13485:2016 |  |  |
| 1 | (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; | Yes | EN ISO 14971:2019  EN ISO 13485:2016 |  |  |
| 1 | (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 | EN ISO 14971:2019  EN ISO 13485:2016  SSI-SOP-17 PMS, etc |  |  |
| 1 | (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 | EN ISO 14971:2019  EN ISO 13485:2016  SSI-SOP-17 PMS, etc |  |  |
| 2 | **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; | Yes | EN ISO 14971:2019  EN ISO 13485:2016 |  |  |
| 2 | (b) where appropriate, take adequate protection measures, including alarms, if necessary, in relation to risks that cannot be eliminated; and | Yes | Vigilance System  EN ISO 14971:2019 |  |  |
| 2 | (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. | Yes | Vigilance System  EN ISO 14971:2019 |  |  |
| 2 | **4.**  Manufacturers shall inform users of any residual risks. | Yes | Vigilance System  EN ISO 14971:2019 |  |  |
| 2 | **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 | Vigilance System  EN ISO 14971:2019 |  |  |
| 2 | (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 | EN ISO 14971:2019  EN ISO 13485:2016 |  |  |
| 4 | **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. | Yes | ISO 9001:2015  EN ISO 13485:2016  EN ISO 14971:2019 |  |  |
| 5 | **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. | Yes | EN ISO 14971:2019  BS EN 15223-1:2021 |  |  |
| 6 | **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. | Yes | EN ISO 14971:2019  MEDDEV 2.7.1 Rev 4 |  |  |
| New | **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. | NA | Not applicable to these products |  |  |
| **II** | **Chapter II**  **Requirements Regarding Design & Manufacture**  **10. Chemical, physical and biological properties** | Yes | EN ISO 14971:2019 |  |  |
| 7.1 | **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; | Yes | EN ISO 14971:2019 |  |  |
| 7.1 | (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; | NA | Not applicable to these products |  |  |
| New | (c) the compatibility between the different parts of a device which consists of more than one implantable part; | NA | Not applicable to these products |  |  |
| New | (d) the impact of processes on material properties; | Yes | EN ISO 14971:2019 |  |  |
| New | (e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; | NA | Not applicable to these products |  |  |
| New | (f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance; | Yes | EN ISO 14971:2019 |  |  |
| New | (g) surface properties; and | Yes  Check RA | EN ISO 14971:2019 |  |  |
| New | (h) the confirmation that the device meets any defined chemical and/or physical specifications. | Yes  Check RA | EN ISO 14971:2019 |  |  |
| 7.2 | **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. | Yes | EN ISO 14971:2019  ISO13485:2016  MDR 2017/745 |  |  |
| 7.3 | **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. | NA | NA |  |  |
| 7.4 | **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 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: | NA | Not applicable to these products |  |  |
| New | (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 Council1, or | NA | Not applicable to these products |  |  |
| New | (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 Council2 or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council3, in accordance with the criteria that are relevant to human health amongst the criteria established therein. | NA | Not applicable to these products |  |  |
| New | **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; \* CMR = Carcinogenic, Mutagenic or toxic to Reproduction | NA | Not applicable to these products |  |  |
| New | (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; | NA | Not applicable to these products |  |  |
| New | (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 | NA | Not applicable to these products |  |  |
| New | (d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4. | NA | Not applicable to these products |  |  |
| 7.5 | **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. | NA | Not applicable to these products |  |  |
| 7.5  New | **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. | NA | Not applicable to these products |  |  |
| 7.5  New | **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 use. | NA | Not applicable to these products |  |  |
| 7.6 | **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. | ? | Ip2X? |  |  |
| New | **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. | Na | Not applicable to these products |  |  |
| 8.1  New | **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, | Yes | EN ISO 14971:2019 |  |  |
| 8.1 | (b) allow easy and safe handling, | Yes | See above |  |  |
| 8.1  New | (c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and | NA | Not applicable to these products |  |  |
| 8.1 | (d) prevent microbial contamination of the device or its content such as specimens or fluids. | NA | Not applicable to these products |  |  |
| 8.1  New | **11.2.** Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation. | Yes  Check RA | EN ISO 14971:2019 |  |  |
| 8.3 | **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. | NA | Not applicable to these products |  |  |
| 8.3 | **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 the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user. | NA | Not applicable to these products |  |  |
| 8.4 | **11.5.** Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods. | NA | Not applicable to these products |  |  |
| 8.5 | **11.6.** Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities. | NA | Not applicable to these products |  |  |
| 8.6 | **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. | Yes | EN ISO 14971:2019 |  |  |
| 8.7 | **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. | NA | Not applicable to these products |  |  |
| 7.4 | **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. | NA | Not applicable to these products |  |  |
| 7.4 | **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 procedure under this Regulation. | NA | Not applicable to these products |  |  |
| 7.4 | **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. | NA | Not applicable to these products |  |  |
| 7.4 | **13. Devices incorporating materials of biological origin** | NA | Not applicable to these products |  |  |
| 7.4 | **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; | NA | Not applicable to these products |  |  |
| 7.4  New | (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; | NA | Not applicable to these products |  |  |
| 7.4  New | (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. | NA | Not applicable to these products |  |  |
| 8.2 | **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 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; | NA | Not applicable to these products |  |  |
| 8.2 | (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; | NA | Not applicable to these products |  |  |
| 8.2 | (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. | NA | Not applicable to these products |  |  |
| 8.2  New | **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. | NA | Not applicable to these products |  |  |
| 9 | **14. Construction of devices and interaction with their environment** |  |  |  |  |
| 9.1 | **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. | YES | EN ISO 14971:2019 |  |  |
| 9.2 | **14.2.** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:  (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; | Yes | EN ISO 14971:2019 EN ISO 20417:2021 |  |  |
| 9.2 | (b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences; | Yes | See above |  |  |
| 9.2  New | (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; | Yes | See above |  |  |
| New | (d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; | Yes |  |  |  |
| New | (e) the risks of accidental ingress of substances into the device; | Yes | EN ISO 14971:2019 | Design review  Risk Assessment | TF02 TCF  TF02 RMP  TF02 RMR  OEM TCF – Section B8.0 – Instructions for Use/Labels |
| 9.2 | (f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and | Yes | EN ISO 14971:2019 EN ISO 20417:2021 IEC 60601 (EMC/LV/Safety Testing) |  |  |
| 9.2 | (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. | NA | Not applicable to these products |  |  |
| 9.3 | **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. | Yes | EN ISO 14971:2019 |  |  |
| New | **14.4.** Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. | Yes | EN ISO 14971:2019 EN ISO 20417:2021 |  |  |
| 9.1 | **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 | EN ISO 14971:2019 |  |  |
| 9.2  New | **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. | YES | EN ISO 14971:2019 |  |  |
| New | **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. | NA to MDR | Not applicable to these products |  |  |
| 10 | **15. Devices with a diagnostic or measuring function** | Yes |  |  |  |
| 10.1 | **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. | Yes |  |  |  |
| 10.3 | **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/EEC1. | Yes |  |  |  |
| 11 | **16. Protection against radiation** | NA | Not applicable to these products |  |  |
| 11.1 | **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. | NA | Not applicable to these products |  |  |
| New | (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. | NA | Not applicable to these products |  |  |
| 11.2.1 | **16.2. Intended radiation**  (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 within an acceptable tolerance. | NA | Not applicable to these products |  |  |
| 11.2.2  New | (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. | NA | Not applicable to these products |  |  |
| 11.  New | **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. | NA | Not applicable to these products |  |  |
| 11.5 | **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. | NA | Not applicable to these products |  |  |
| 11.5.1 | (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. | NA | Not applicable to these products |  |  |
| 11.5.2 | (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. | NA | Not applicable to these products |  |  |
| 11.5.3 | (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. | NA | Not applicable to these products |  |  |
| 12  New | **17. Electronic programmable systems – devices that incorporate electronic programmable systems and software that are devices in themselves** | Yes | ISO 62304 |  |  |
| 12.1  New | **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 | ISO 62304 |  |  |
| 12.1a | **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 | ISO 62304 |  |  |
| New | **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 |  |  |  |
| New | **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. | Yes |  |  |  |
| 12  New title | **18. Active devices and devices connected to them** | Yes |  |  |  |
| 12.1  New | **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 | IEC 60601  EMC/LV/Safety Testing |  |  |
| 12.2 | **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. | Yes | IEC 60601  EMC/LV/Safety Testing |  |  |
| 12.3 | **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. | NA | NA |  |  |
| 12.4 | **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. | ? |  |  |  |
| 12.5 | **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. | Yes | IEC 60601  EMC/LV/Safety Testing |  |  |
| 12.5 | **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. | Yes | IEC 60601  EMC/LV/Safety Testing |  |  |
| 12.6 | **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. | Yes | IEC 60601  EMC/LV/Safety Testing |  |  |
| New | **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. | Yes |  |  |  |
| 12  New Title | **19. Particular requirements for active implantable devices** | NA | Not applicable to these products |  |  |
| New | **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, | NA | Not applicable to these products |  |  |
| New | (b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and | NA | Not applicable to these products |  |  |
| New | (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. | NA | Not applicable to these products |  |  |
| New | **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. | NA | Not applicable to these products |  |  |
| New | **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. | NA | Not applicable to these products |  |  |
| New | **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. | NA | Not applicable to these products |  |  |
| 12.7 | **20. Protection against mechanical and thermal risks** | Yes |  |  |  |
| 12.7.1 | **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. | Yes | EN ISO 14971:2019 |  |  |
| 12.7.2 | **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. | Yes | EN ISO 14971:2019 |  |  |
| 12.7.3 | **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. | NA | Not applicable to these products |  |  |
| 12.7.4 | **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. | Yes | EN ISO 14971:2019  IEC 60601 |  |  |
| New | **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. | Yes | ISO 13485:2016  EN ISO 14971:2019 |  |  |
| New | **20.5** 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. | Yes | ISO 13485:2016  EN ISO 14971:2019 |  |  |
| 12.7.5 | **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. | Yes | ISO 13485:2016  EN ISO 14971:2019  IEC 60601 |  |  |
| 12.8 | **21.** **Protection against the risks posed to the patient or user by devices supplying energy or substances** | NA | Not applicable to these products |  |  |
| 12.8.1 | **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. | NA | Not applicable to these products |  |  |
| 12.8.2 | **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. | NA | Not applicable to these products |  |  |
| 12.9 | **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. | Yes | EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| New Title | **22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons** | Yes | EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| New | **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 easy for the lay person to understand and apply. | Yes | EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| New | **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. | Yes | EN ISO 14971:2019  EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| New | **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. | Yes | EN ISO 13485:2016  EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| 13 | **Chapter III**  **Requirements Regarding the Information Supplied with the Device**  **23. Label and instructions for use** | Yes | EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| 13.1  New | **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. | Yes  Check/Add to RA | EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| 13.1 | (b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices. | Yes | EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| New  (see UDI –  Annex VI) | (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  Add to RA | MDR (EU) 2017/745  Annex VI |  |  |
| 13.1 | (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 | EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| New | (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  Add to RA | EN ISO 14971:2019  EN ISO 15223-1:2021 |  |  |
| New | (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  Add to RA | EN ISO 15223-1:2021 |  |  |
| 13.3 k | (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 | EN ISO 15223-1:2021 |  |  |
| 13.2 | (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. | Yes | EN ISO 15223-1:2021 |  |  |
| 13.3 b | **23.2. Information on the label**  The label shall bear all of the following particulars:  (a) the name or trade name of the device; | Yes | EN ISO 13485:2016 |  |  |
| 13.3 b | (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 | EN ISO 13485:2016 |  |  |
| 13.3 a | (c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business; | Yes | EN ISO 13485:2016  EN ISO 15223-1:2021 |  |  |
| 13.3 a | (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; | YES | We are now NOT based within the EU  MDR 2017/745 |  |  |
| 13.3 n | (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; | NA | Not applicable to these products |  |  |
| 13.3 i  New | (f) where applicable, information labelled in accordance with Section 10.4.5.; | NA | Not applicable to these products |  |  |
| 13.3 d | (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; | Yes | EN ISO 13485:2016  EN ISO 15223-1:2021 |  |  |
| New  (see UDI –  Annex VI) | (h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII; | Yes  Add to RA | MDR (EU) 2017/745  Annex VI |  |  |
| 13.3 e  New | (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; | NA | Products don’t have a defined shelf life |  |  |
| 13.3 l | (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; | NA | Products don’t have a defined shelf life |  |  |
| 13.3 i | (k) an indication of any special storage and/or handling condition that applies; | NA | Not applicable to these products |  |  |
| 13.3 c & 13.3 m | (l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method; | NA | Not applicable to these products |  |  |
| 13.3 k | (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; | Yes | EN ISO 15223-1:2021 |  |  |
| 13.3 f | (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; | NA | Not applicable to these products |  |  |
| New | (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; | NA | Not applicable to these products |  |  |
| 13.3 g | (p) if the device is custom-made, the words 'custom-made device'; | NA | Not applicable to these products |  |  |
| 13.3 h  New | (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  Add to Label | EN ISO 15223-1:2021 |  |  |
| New | (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; | NA | Not applicable to these products |  |  |
| New | (s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number. | NA | Not applicable to these products |  |  |
| 13.3 c  New  Title | **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, | NA | Not applicable to these products |  |  |
| 13.3 c  New | (b) a declaration that the device is in a sterile condition, | NA | Not applicable to these products |  |  |
| 13.3 c & 13.3 m  New | (c) the method of sterilisation, | NA | Not applicable to these products |  |  |
| 13.3 c & 13.a  New | (d) the name and address of the manufacturer, | NA | Not applicable to these products |  |  |
| 13.3 c & 13.3 b  New | (e) a description of the device, | NA | Not applicable to these products |  |  |
| 13.3 c & 13.3 h | (f) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations', | NA | Not applicable to these products |  |  |
| 13.3 c & 13.3 g | (g) if the device is custom-made, the words 'custom-made device', | NA | Not applicable to these products |  |  |
| 13.3 c & 13.3 l | (h) the month and year of manufacture, | NA | Not applicable to these products |  |  |
| 13.3 c & 13.3 e | (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 | NA | Not applicable to these products |  |  |
| 13.3 c & 13.3 j | (j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use. | NA | Not applicable to these products |  |  |
| 13.6 a | **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; | Yes | EN1041:2008\*  (now BS EN 1041:2013) |  |  |
| 13.6 b | (b) the device's intended purpose with a clear specification of indications, contraindications, the patient target group or groups, and of the intended users, as appropriate; | Yes | EN ISO 13485:2016 |  |  |
| 13.6 k  New | (c) where applicable, a specification of the clinical benefits to be expected. | YES | EN1041:2008\*  (now BS EN 1041:2013) |  |  |
| 13.6 k  New | (d) where applicable, links to the summary of safety and clinical performance referred to in Article 32; | Yes | EN ISO 13485:2016  EN ISO 15223-1:2021  EN ISO 14971:2019 |  |  |
| 13.6 d &  13.6 k  New | (e) the performance characteristics of the device; | Yes | EN ISO 13485:2016  EN ISO 15223-1:2021  EN ISO 14971:2019 |  |  |
| 13.6 c &  13.6 c & 13.6 k  New | (f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories; | Yes | EN ISO 13485:2016  EN ISO 15223-1:2021  EN ISO 14971:2019 |  |  |
| 13.6 k  New | (g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard; | Yes | EN ISO 13485:2016  EN ISO 15223-1:2021  EN ISO 14971:2019 |  |  |
| 13.6 p | (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; | Yes |  |  |  |
| 13.6 d & 13.6 g &  13.6 i  New | (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; | Yes | EN ISO 13485:2016  EN ISO 15223-1:2021  EN ISO 14971:2019 |  |  |
| New | (j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons; | NA | Not applicable to these products |  |  |
| 13.6 d & 13.6 g &  13.6 i  New | (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; | Yes | EN ISO 13485:2016  EN ISO 15223-1:2021  EN ISO 14971:2019 |  |  |
| 13.6 g | (l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use; | NA | Not applicable to these products |  |  |
| 13.3 m &  13.6 i | (m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation; | NA | Not applicable to these products |  |  |
| New  13.3 j | (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; | Yes | EN ISO 13485:2016  EN ISO 15223-1:2021  EN ISO 14971:2019 |  |  |
| New | (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; | NA | Not applicable to these products |  |  |

**Compiled By:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and title Date:

**Approved By:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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