MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
I. General requirements	**I. General requirements**	
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will 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.	1. Devices shall achieve the performance intended by the manufacturer and 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.	*Requirement reorganized* A specific reference is now made to state of the art.
	1aa. The requirements in this annex to reduce risks as far as possible mean reduce risks as far as possible without adversely affecting the risk benefit ratio. 1a. The manufacturer shall establish, implement, document and maintain a risk management system. Risk management is a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic update. It requires a manufacturer to: (a) establish and document a risk management plan for each device; (b) identify and analyse the known and foreseeable hazards associated with each device; (c) estimate and evaluate the associated risks occurring during the intended use and during reasonably foreseeable misuse; (d) eliminate or control these risks according to the requirements of Section 2; (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system on hazards and their frequency of occurrence, estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability. (f) based on the evaluation of the impact of information from the production phase or the post market surveillance system if necessary amend control measures in line with the requirements of Section 2.	New requirement The text now has a stronger connection to ISO 14971

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:	2. risk control measures adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the 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, the manufacturer shall apply the following principles in the priority order listed:	Partial change
• eliminate or reduce risks as far as possible (inherently safe design and construction),	(b) eliminate or reduce risks as far as possible through safe design and manufacture;	No change
• where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	c) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and	No change
• inform users of the residual risks due to any shortcomings of the protection measures adopted.	d) provide information for safety warnings / precautions / contraindications) and, where appropriate, training to users.	Similar Requirement completed for clarity
	d) (continue) The manufacturer shall inform users of any residual risks.	New requirement
1) (continue) This shall include: - reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	2b. In eliminating or reducing risks related to use error the manufacturer shall apply the following principles: – reducing 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	Similar Requirement completed for clarity
- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	– consideration of 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).	Partial change
3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.		
4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients 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.	3. The characteristics and performances of the 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.	Similar Requirement completed for clarity

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	4. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.	Similar Requirement completed for clarity
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	5. 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 of the achieved performance of the device during normal conditions of use.	Similar Requirement completed for clarity
	6. For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, the general safety requirements set out in Sections 1 and 5 shall be understood that the device, when used under the conditions and for the purposes intended, shall not present any risk or 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.	New Requirement
6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.		Requirement Deleted Clinical evaluation required per Article 49 and Annex XIII
II. Requirements regarding design and construction	**II. Requirements regarding design and manufacturing**	
7. Chemical, physical and biological properties 7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to:	**7. Chemical, physical and biological properties** *7.1 The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I 'General Requirements'. Particular attention shall be paid to:*	No change
the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	(a) the choice of materials and substances used, particularly as regards toxicity and, where appropriate, flammability;	No change
the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.	(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;	Similar Requirement completed for clarity
	(ba) the compatibility between the different parts of a device which consists of more than one implantable parts;	New requirement
	(bb) the impact of processes on material properties;	New requirement
where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand.	(c) where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand;	No change

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	(d) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance , wear resistance and fatigue resistance ;	New requirement
	(e) surface properties;	New requirement
	(f) confirming that the device meets any defined chemical and/or physical specifications.	New requirement
7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	7.2. The 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 and to the duration and frequency of exposure.	Similar Requirement completed for clarity
7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	7.3. The 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 according to the provisions and restrictions governing these medicinal products and that both the performance of the medicinal products and of the devices are maintained in accordance with their respective indications and intended use.	Similar Requirement completed for clarity
7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances (1). If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labeled on the	**7.4. Substances** 7.4.1. 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, processing residues, that may be released from the device. Devices , or those parts thereof or those materials used therein: - that are invasive and to come into direct contact with the human body, or	Similar Requirement completed for clarity
	- that (re)administer medicines, body liquids or other substances, including gases, to/from the body, or	No change
	- that transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,	No change
	shall only contain the following substances in a concentration above 0.1% weight by weight (w/w) when justified pursuant to Section 7.4.2:	New requirement

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	(a) substances which are carcinogenic, mutagenic or toxic to reproduction 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 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006,	Similar Requirement completed for clarity
	(b) substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)42 or in accordance with those criteria that are relevant to human health of the criteria established in the delegated act adopted by the Commission pursuant article 5(3), first paragraph, of Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products.	New requirement
	7.4.2. Justification regarding the presence of CMR substances and/ or endocrine disruptors The justification for the presence of such substances shall be based upon: - An analysis and estimation of potential patient or user exposure to the substance; - An analysis of possible alternative substances, materials or designs, including, when available, information about independent research, peer reviewed studies, scientific opinions from relevant Scientific Committees and an analysis of the availability of such alternatives; - Argumentation why possible substance and/ or material substitutes or design changes, if available, are inappropriate to maintain 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 nursing women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; - Where applicable and available, the latest relevant Scientific Committee guidelines in accordance with Sections 7.4.3. and 7.4.4..	New requirement

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	7.4.3. Guidelines on phthalates For the purposes of this article the Commission shall, as soon as possible and at the latest one year after the date of entry into force of this regulation, provide the relevant Scientific Committee with a mandate to prepare guidelines that shall be ready before the date of application of this regulation. 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 7.4.1.. The benef/trisk assessment shall take into account the intended purpose and context of the use of the device, available alternative substances and alternative materials, designs and/ or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every 5 years, the guidelines shall be updated.	New requirement
	7.4.4. Guidelines on other CMR or endocrine disrupting substances Subsequently, the Commission shall mandate the relevant Scientific Committee to prepare guidelines as referred to in Section 7.4.3. also for other substances referred to in Points (a) and (b) of Section 7.4.1., where appropriate.	New requirement
	7.4.5. Labelling If devices, parts thereof or materials used therein as referred to in Section 7.4.1. contain substances referred to in points (a) or (b) of Section 7.4.1. in a concentration above 0.1% weight by weight (w/w), these devices 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 nursing women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.	New requirement
7.6. Devices must be designed and manufactured in such a way as to reduce, as much as possible, 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.	7.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible 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 change
	7.6. 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	New requirement

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	come into contact with the intact skin only. Special attention shall be given to nanomaterials.	
8. Infection and microbial contamination 8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must	**8. Infection and microbial contamination** 8.1. Devices and 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:	Slight change
	(aa) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,	New Requirement
8.1 (continue) allow easy handling and,	(a) allow easy and safe handling,	Similar
8.1 (continue) where necessary, minimize contamination of the device by the patient or vice versa during use.	(b) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use,	Similar Requirement reorganized for clarity
	(c) prevent microbial contamination of the device or its content such as specimens or fluids.	New requirement
	8.1a. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	New requirement
	8.2. Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	New requirement
8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	8.3. Devices delivered in a sterile state shall be designed, manufactured and packaged according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened at the point of use. These measures shall ensure that the integrity of the sterile packaging is clearly evident to the final user.	Similar Requirement reorganized for clarity
8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	8.4. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by appropriate, validated methods.	Similar Partial change
8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	8.5. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	Similar Partial change
8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial	8.6. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be	Similar

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	suitable taking account of the method of sterilisation indicated by the manufacturer.	
8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	8.7. The labelling of the device shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition additional to the symbol used to indicate that a product is sterile.	Partial change May require creation of a new symbol.
7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 2001/83/EC.	**9. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or combination of substances that are absorbed by or locally dispersed in the human body** es referred to in the first subparagraph of Article 1(4), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning 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 laid down in the applicable conformity assessment procedure in this Regulation.2. Devices that are 9. 9.2. 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 shall comply, where applicable and 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 laid down in the applicable conformity assessment procedure in this Regulation.	Similar Requirement reorganized and clarified
	10. Devices incorporating materials of biological origin 10.1. For devices manufactured utilising tissues or cells, or their derivatives, of human origin which are non-viable or rendered non-viable covered by this Regulation in accordance with point (ea) of Article 1(2) the following applies:	New requirement
	(a) Donation, procurement and testing of tissues and cells of human origin used for the manufacture of devices shall be made in accordance with Directive 2004/23/EC.	New requirement
	(b) The processing, preservation and any other handling of those tissues and cells 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	New requirement

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	course of the manufacturing process.	
	(c) It shall be ensured that the traceability system for devices manufactured utilising those human tissues or cells is complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.	New requirement
8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals.	10.2. For devices manufactured utilising tissues or cells, or their derivatives, of animal origin which are non-viable or rendered non-viable the following applies: (a) Where feasible taking into account the animal species, tissues and cells of animal origin 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.	Partial change
8.2 (continue) Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	(b) Sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin 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.	Similar Partial change
	(c) In the case of devices manufactured utilising tissues or cells of animal origin as referred to in Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin44 the particular requirements laid down in that Regulation shall apply.	New requirement
	10.3. For devices manufactured utilising other non-viable biological substances the following applies: In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and,	New requirement

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	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.	
9. Construction and environmental properties 9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	**11. Construction of devices and interaction with their environment** 11.1. 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 avoid misconnection.	Similar Requirement completed for clarity See 16.4 for similar requirement
9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: • the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,	11.2. 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;	Similar
• risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,	(c) 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;	Partial change
	(d) 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;	New requirement
	(e) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;	New requirement Required as part of IEC 62304.
	(f) the risks of accidental ingress of substances into the device;	New requirement May be redundant with 7.5
• the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,	(g) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	No change

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
• 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.	(h) 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 change
9.3. Devices must 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 must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	11.3. 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 whose intended use includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.	No change
	11.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	New requirement
	11.5. 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.	New requirement
	11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or related waste substances by the user, patient or other person. To that end, manufacturers shall investigate and test procedures and measures by which their devices can be safely disposed after use. These procedures shall be described in the instructions for use.	New requirement
10. Devices with a measuring function 10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.	**12. Devices with a diagnostic or measuring function** 12.1. 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.	Partial change
10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	11.6 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.	Similar Partial change
10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).	12.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC	Similar Partial change
11. Protection against radiation	**13. Protection against radiation**	Similar

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
11.1. General 11.1.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	13.1. General (a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Partial change
	(b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall give detailed information as to the nature of the emitted radiation, 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 testing, the performance testing and the acceptance criteria, the maintenance procedure shall also be specified.	New requirement
11.2. Intended radiation 11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	13.2 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 in 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.	Similar Requirement completed for clarity
11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	(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.	Similar Requirement completed for clarity
11.3. Unintended radiation 11.3.1. 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.	13.3 Unintended radiation 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.	Requirement completed
11.4. Instructions 11.4.1. The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and		

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
of eliminating the risks inherent in installation.		
11.5. Ionizing radiation	13.4. Ionising radiation (aa) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Council Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.	New requirement
11.5.1. Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	(a) 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.	Similar Requirement completed
11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	(b) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.	No change
11.5.3. Devices emitting ionizing radiation, 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 and energy and where appropriate the quality of radiation.	(c) Devices emitting ionising radiation, 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 change
12. Requirements for medical devices connected to or equipped with an energy source 12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	**14. Electronic programmable systems - Devices that incorporate electronic programmable systems and software that are devices in themselves** 14.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance according to the 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.	Similar Requirement completed for clarity Partial change
12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.	14.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.	Partial change
	14.3. Software referred to in this Section that are intended to be used in combination with mobile computing platforms shall be designed and	New requirement

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	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 to level of light or noise).	
	14.3a. The manufacturer shall describe minimum requirements on hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.	New requirement
	15. Active devices and devices connected to them 15.1. 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.	New requirement
12.2. Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	15.2. Devices where the safety of the patients 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 if, or if necessary before, the capacity of the power supply becomes critical.	Partial change Already covered by ISO EN 80601-2-xx
12.3. Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	15.3. Devices where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.	No change
12.4. Devices intended to monitor one or more clinical parameters of a patient must 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.	15.4. 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 change
12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	15.5. 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 this or other devices or equipment in the intended environment.	No change
	15.6. Devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.	New requirement
12.6. Protection against electrical risks Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	15.7. 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.	Similar Requirement completed for clarity
	15.8. Devices shall be designed and manufactured in such a way as to avoid unauthorized access to the device as far as possible that would hamper the	New requirement

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	device to run as intended.	
	15a. Particular requirements for active implantable devices 15a.1. Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible: - risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices, - risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, - 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.	Compare with the AIMD Annex I.
	15a.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, - the reliability of the source of energy.	Compare with the AIMD Annex I.
	15a.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.	Compare with the AIMD Annex I.
	15a.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 year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.	Compare with the AIMD Annex I.
12.7. Protection against mechanical and thermal risks 12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	**16. Protection against mechanical and thermal risks** 16.1. Devices shall be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	No change
12.7.2. Devices must be designed and manufactured in such a way as to	16.2. Devices shall be designed and manufactured in such a way as to reduce	No change

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
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.	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.	
12.7.3. Devices must 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.	16.3. 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 change
12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	16.4. 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 change Similar issues are addressed in 11.1
	16.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	New requirement
12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	16.6. Accessible parts of the 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 change
12.8. Protection against the risks posed to the patient by energy supplies or substances 12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	**17. Protection against the risks posed to the patient or user by supplied energy or substances** 17.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to assure the safety of the patient and of the user.	Similar
12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	17.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount of energy or substances 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.	Similar

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
12.9. The function of the controls and indicators must 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 must be understandable to the user and, as appropriate, the patient.	17.3. 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 change
	18. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons 18.1. 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 reasonably be 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.	New requirement Covered by EN 60601-1-11 and EN ISO 62366-1
	18.2. 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, and - 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.	New requirement Covered by EN 60601-1-11 and EN ISO 62366-1
	18.3. 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.	New requirement Covered by EN 60601-1-11 and EN ISO 62366-1
13. Information supplied by the manufacturer 13.1. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use.	**III. Requirements regarding the information supplied with the device** **19. Label and instructions for use** 19.1. 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 communicate safety and performance related information to the user, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the	*Requirement reorganized*

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	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.	*New Requirement*
As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.	(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. 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.	*Requirement reorganized (clarified)*
Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	(c) By way of exception, no such instructions for use are needed for devices in class I and IIa if they can be used safely without any such instructions .	*No change*
	(d) 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.	*New Requirement*
	(e) 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 Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices46.	*New Requirement*
	(f) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contraindications, precautions or warnings in the information supplied by the manufacturer.	*New Requirement*
13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	(g) Where appropriate, this information shall take the form of internationally recognized symbols. Any symbol or identification colour used shall conform to the harmonized standards or CS. In areas for which no standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.	*No change*
13.3. The label must bear the following particulars: (a) the name or trade name and address of the manufacturer.	19.2. Information on the label The label shall bear the following particulars :	*No change*

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	(a) The name or trade name of the device.	
(b) the details strictly necessary for the user to identify the device and the contents of the packaging;	(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.	*Partial change (highlight changed text,)*
	(c) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business.	*New Requirement* Required by IEC 60601-1 so not really new
13.2 (continue) For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate;	(d) If the manufacturer has his registered place of business outside the Union, the name and address of the authorized representative	*No change*
	(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, or their derivatives, of animal origin as referred to in Commission Regulation (EU) No 722/2012.	*New Requirement*
	(fa) Where applicable, labelling in accordance with section 7.4.5..	*Requirement reorganized* Was a requirement in 7.5 of MDD but now also added to labeling section of MDR
(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	(g) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate.	*No change*
	(h) the unique device identification (UDI) carrier according to Article 24 and Annex V Part C.	*New Requirement* UDI – may be different than FDA UDI requirements
(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	(i) An unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month, where this is relevant.	*Partial change*

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;	(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 batch or serial number, provided the date is clearly identifiable.	*Requirement reorganized (clarified)*
(i) any special storage and/or handling conditions;	(k) An indication of any special storage and/or handling condition that applies.	*No change*
(c) where appropriate, the word 'STERILE'; (m) where applicable, method of sterilization.	(l) If the device is supplied sterile, an indication of its sterile state and the sterilization method.	*No change*
(k) any warnings and/or precautions to take;	(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.	*Requirement reorganized (clarified)*
(f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;	(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 change*
	(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.	*New Requirement*
(g) if the device is custom-made, the words 'custom-made device';	(p) If the device is custom made, the words “custom – made device”.	*No change*
(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	(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".	*Partial change*
	(r) In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice or applied on 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(s) responsible for achieving the principal intended action(s)	*New Requirement*
	(s) for active implantable devices the serial number and for other implantable devices the serial number or the batch number.	*New Requirement* Added IVD
(j) any special operating instructions;		*Moved to 19.3 g)*
(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.		*See 19.3 p)*
	19.2a. On the sterile packaging:	*Requirement reorganized*

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	The following particulars shall appear on the sterile packaging: (a) an indication permitting the sterile packaging to be recognized as such, (b) a declaration that the device is in a sterile condition, (c) the method of sterilization, (d) the name and address of the manufacturer, (e) a description of the device, (f) if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations', (g) if the device is custom-made, the words 'custom-made device', (h) the month and year of manufacture, (i) an indication of the time limit for using or implanting the device safely, (j) an instruction to check the Instructions For Use for what to do if the sterile packaging is damaged etc.	*(clarified)* See also 19.2 (l)
13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.		*See 19.3 b)*
13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.		*See 19.1 j)*
13.6. Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e);	19.3. Information in the instructions for use The instructions for use shall contain the following particulars: (a) The particulars referred to in points 19.2. (a), (c), (e), (f), (fa), (k), (l), (n) and (r).	*Requirement reorganized (clarified)*
	(b) The device's intended purpose with clear specification of target group(s), indications, contraindications including the intended user, as appropriate.	*Moved – was MDD 13.4*
	(bb) where applicable, a specification of clinical benefits to be expected.	*New requirement*
	(bc) where applicable, links to the summary of safety and clinical performance according to Article 26.	*New requirement*
(b) the performances referred to in Section 3 and	(c) The performance characteristics of the device .	*No change*
	(ca) Where applicable, information allowing the healthcare professional to	*New Requirement*

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	verify if the device is suitable and select the corresponding software and accessories.	
(b) (continue) any undesirable side-effects;	(d) Any residual risks, contraindications and any undesirable side-effects, including information to be conveyed to the patient in this regard.	*Requirement reorganized (clarified)*
	(e) 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.	*New requirement* See also MDR section 12
(d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;	(f) Details of any preparatory treatment or handling of the device before it is ready for use or during its use (e.g. 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.	*Requirement reorganized*
	(g) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons.	*Requirement reorganized* Was in MDD 13.2j)
	(h) 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 preventative 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; - methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing devices.	*New Requirement*
(e) where appropriate, information to avoid certain risks in connection with implantation of the device;		*New requirement*
(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;		*See 11.2g)*
(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	(i) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use.	*No change*
(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.	(k) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State(s) where the device is placed on the market. Information shall be provided to identify	*Partial change (highlight changed text,)*

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.	
Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I;	(j) If the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation.	*No change*
	(ka) 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.	*New requirement*
If the device bears an indication that the device 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. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;	(l) 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 risk management documentation, where these characteristics and technical factors shall be addressed in detail. If in accordance with point (c) of Section 19.1 no instructions for use are needed, the information shall be made available to the user upon request.	*Requirement reorganized (clarified)* Added reference to risk management
(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);		*See 19.3 f)*
(j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	(n) If the device emits radiation for medical purposes: - detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; - the means of protecting the patient, user, or other person from unintended radiation during use of the device.	*Partial change (highlight changed text,)*
The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: (k) precautions to be taken in the event of changes in the performance of the device;	(o) Information that allows the user and/or patient to be informed and, where relevant, to brief the patient of any warnings, precautions, contra - indications, measures to be taken and limitations of use regarding the device. This information shall cover, where appropriate: - warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;	*No change*
(l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	- warnings, precautions and/or measures to be taken in regards to 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;	*Requirement reorganized (clarified)* Added more specifics than were in MDD

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	- warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);	*Requirement reorganized (clarified)* See also 11.2 c)
(m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;	- if the device is intended to administer medicinal products, tissues or cells, or their derivatives, of human or animal origin or biological substances, any limitations or incompatibility in the choice of substances to be delivered;	*No change*
(n) precautions to be taken against any special, unusual risks related to the disposal of the device;	(p) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate: - infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin); - physical hazards (e.g. from sharps).	*Partial change (highlight changed text,)*
(o) medicinal substances or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;	- 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;	*No change*
	- precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user;	*New requirement*
	(oa) 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, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side effects and risks relating to overdose.	*New requirement*
	(ob) in the case of implantable devices the overall qualitative and quantitative information on the materials and substances to which patients can be exposed.	*New requirement*
	(q) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.	*New requirement*
	(r) For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, information regarding the absence of a clinical benefit and	*New requirement*

MDD Essential Requirement – Annex I	MDR General Safety and Performance Requirements – Annex I	Change Overview
	the risks related to the use of the device.	
(p) degree of accuracy claimed for devices with a measuring function.		*Moved* See 19.3e MDR
(q) date of issue or the latest revision of the instructions for use	(s) 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.	*No change*
	(t) 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 where the user and/or patient is established.	*New requirement*
	(u) Information to be supplied to the patient with an implanted device according to Article 16.	*New requirement* Implantables