THE ULTIMATE GUIDE

EU MDR GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (GSPR)

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Overview

With the European Medical Device Regulation (MDR) looming, medical device companies are focusing on ensuring compliance with the new regulations. One of those key aspects of compliance is to ensure your devices conform to the General Safety and Performance Requirements (GSPR). This guide provides you with some practical guidance on how to meet those requirements.

Timeline

The EU MDR application is just coming fast. In fact, all applications under the new EU MDR must be made no later than May 26, 2021. Below is a high-level overview of key dates.

Terminology

What's the difference between Essential Requirements, General Safety and Performance Requirements (GSPR), and Essential Principles. In order to have a meaningful dialogue, let's first discuss the three (3) main terms used in industry.

#1 Essential Requirements

The 'Essential Requirements' is the backbone for establishing conformity with the Medical Device Directive (MDD 93/42/EEC) and the Active Implantable Medical Device Directive (AIMDD 90/385/EEC). Detailed within Annex I of the MDD and AIMDD, the 'Essential Requirements' laid out the requirements that devices must meet in order to state compliance to the directives. With the implementation of the new EU Medical Device Regulation (MDR 2017/745), the 'Essential Requirements' will become superseded by the new EU MDR General Safety and Performance Requirements (GSPRs).

#2 Essential Principles

The IMDRF laid out Essential Principles requirements in a document entitled Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices. From a high-level perspective, three basic tenets make up these 'Essential Principles':

- A device must be designed to be safe and perform effectively throughout its lifecycle.
- Device manufacturers must maintain all design characteristics.
- Devices must be used in a way that is consistent with how it was designed.

Many countries use the term 'Essential Principles' when compiling the documentation required to determine compliance to the law. For instance, the Australian Therapeutic Goods Administration (TGA) uses the term 'Essential Principles Checklist'. Regardless of the term used, Essential Principles are of similar nature and overlap many of the Essential Requirements and new GSPRs.

#3 General Safety & Performance Requirements (GSPR)

As of May 26, 2021, medical device manufacturers must start to comply with Annex I - General Safety and Performance Requirements (GSPRs) of the new EU Medical Device Regulation (MDR 2017/745). GSPRs are specific to the European MDR and IVDR. If you hear any other term (i.e. Essential Principles), it most likely means it is not referencing the European market.

EU Medical Device Regulation Annex I (MDR 2017/745)

Annex I of the EU MDR details the specific requirements of the General Safety and Performance Requirements (GSPRs)

The new EU MDR GSPRs are broken down into three (3) chapters:

CHAPTER 1
General Requirements

CHAPTER 2
Requirements Regarding Design and Manufacture

CHAPTER 3
Requirements Regarding the Information Supplied with the Device

CHAPTER 1
General Requirements

Both the EU MDR and the EU IVDR outline General Safety and Performance Requirements (GSPRs) in great detail for medical device designers and manufacturers. The general requirements for each overlap with each other and consist of the following:

- Devices must perform in a way that aligns with the intended design.
- They must not compromise the health or safety of a patient, user, or any other person associated with the device.
- Risks must be reduced as much as possible, but not so much that they negatively affect the ratio of benefit to risk.
- Device manufacturers must implement and maintain a thorough, well-documented, and evaluative risk management system that continues to be updated throughout the life cycle of a device.
- Manufacturers and designers must include any necessary measures for protecting users in cases where risks cannot be completely eliminated.
- Manufacturers must provide users with information about any potential risks that remain. This information must be clear, easy to understand, and considerate of the users' technical knowledge level, use environment, and any applicable medical conditions.
- Devices must withstand the stresses of normal use for the duration of their lifecycle.
- Devices must be designed, manufactured, and packaged in a way that protects them from damage during transport and storage.
- When it comes to risks and negative side effects that are known and foreseeable, designers and manufacturers must make every effort to minimize negative outcomes. They must also ensure that potential risks are acceptable when compared to the potential benefits of a device to its users.

CHAPTER 2
Requirements Regarding Design and Manufacture

The GSPRs also provide key details regarding specific information about the design and manufacture of medical devices. As it relates to design inputs, the GSPRs provide highly-detailed requirements relating to a device's:

- Chemical, physical and biological properties
- Potential for infection or microbial contamination
- Use of substances that are considered to be a medicinal product or that the human body otherwise absorbs or disperses
- Incorporation of biological materials
- Interaction with its environment
- Ability to diagnose or provide measurements
- Radioactive properties
- Systems that are electronically programmable
- Capability for being active and connected to other devices
- Capability for being active and implantable
- Ability to withstand mechanical and thermal risks
- Ability to safely supply energy or substances to the user or patient
- Ability to be used by lay persons

Within each of these line items, the GSPRs outline key details to which designers and manufacturers must adhere where the requirements are applicable.

CHAPTER 3
Requirements Regarding the Information Supplied with the Device

The final key area of governance within the GSPRs relates to specific information a manufacturer must supply with a device. The general requirements for this information states that, "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." The requirements provide further detail as far as location-specific information such as the information that must be provided on:

- The device label
- The user instructions
- The packaging of a device that is intended to maintain its sterile condition

EU Medical Device Regulation Annex II (MDR 2017/745)

In addition to the specific requirements identified within **Annex I of the EU MDR, Annex II - Technical Documentation** identifies additional requirements. Specifically, **Section 4 - General Safety and Performance Requirements** states:

> *"the documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:*
>
> *(a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;*
> *(b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;*
> *(c) the harmonised standards, CS or other solutions applied; and*
> *(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation."*

Let's break this down into each part.

Requirement
(a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;

What needs to be documented for the requirements that apply or the requirements that do not apply?

Each and every GSPR should be assessed in its own right. When a requirement applies, a simple statement may be made that this requirement applies to the device. In practice this is often achieved through the use of a checklist or table, with a column for applicability and a Yes/No answer against each requirement. When a requirement applies, you can move on to the other parts of demonstrating conformity regarding methods used and standards applied.

When a requirement is not applicable, a statement must be made to that effect, i.e. a 'No' in the applicability column. Additionally, it must be properly justified, even if it appears obvious to you. Such a justification may be something like 'The device is not powered and is therefore not an active device. This requirement does not apply'. The justification should clearly state why the requirement has been deemed not to apply so that a third party can understand your reasoning.

Requirement
(b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;

What is meant by "method or methods used"?

This relates to the way you complied with that GSPR, historically it would be listed as a standard or other documentation reference that you have applied to demonstrate compliance, however the question of 'method or methods used' is new to the MDR and it is expected that a verbal description be provided such as:

i. Risk analysis weighed against clinical evaluation benefit
ii. Performance intended demonstrated by design requirements, verification and validation

Requirement
(c) the harmonised standards, CS or other solutions applied;

What are harmonized standards, common specifications (CS), and "other solutions"?

Harmonised Standards

These are standards that have been specifically developed and assessed for compliance to a regulation or directive. They are published in the Official Journal of the European Union (sometimes just referred to as 'the OJ') and if you comply with these standards then there is a 'presumption of conformity' with that directive or regulation to which they have been harmonised. These harmonised standards can only be created by a recognised European Standard Organisation (such as CEN or CENELEC). When a standard is harmonized, an annex is added that describes how the standard conforms to the directive or regulation. When using harmonised standards you should make sure that you understand how the standard conforms so that you do not claim compliance when the standard either does not meet that requirement or only partially meets that requirement.

If a standard does not meet a certain requirement of the directive or regulation, or indeed only partially meets it, then you must employ additional mechanisms for compliance. If a harmonised standard meets part of a directive or regulation, then by complying with that standard you also fully meet the corresponding requirement(s) (At the time of this writing, there are no harmonised standards for the MDR and many are under current development). In this case, using an MDD harmonised standard and documenting a justification for doing so (i.e. how you believe the standard demonstrates compliance with the GSPRs), should provide sufficient evidence.

Common Specifications

Common Specifications are a new concept in the MDR. They allow the European Union to bring in additional requirements that must be met in order to claim compliance. You can think of Common Specifications as a 'Super Standard'. The definition of a Common Specification is:

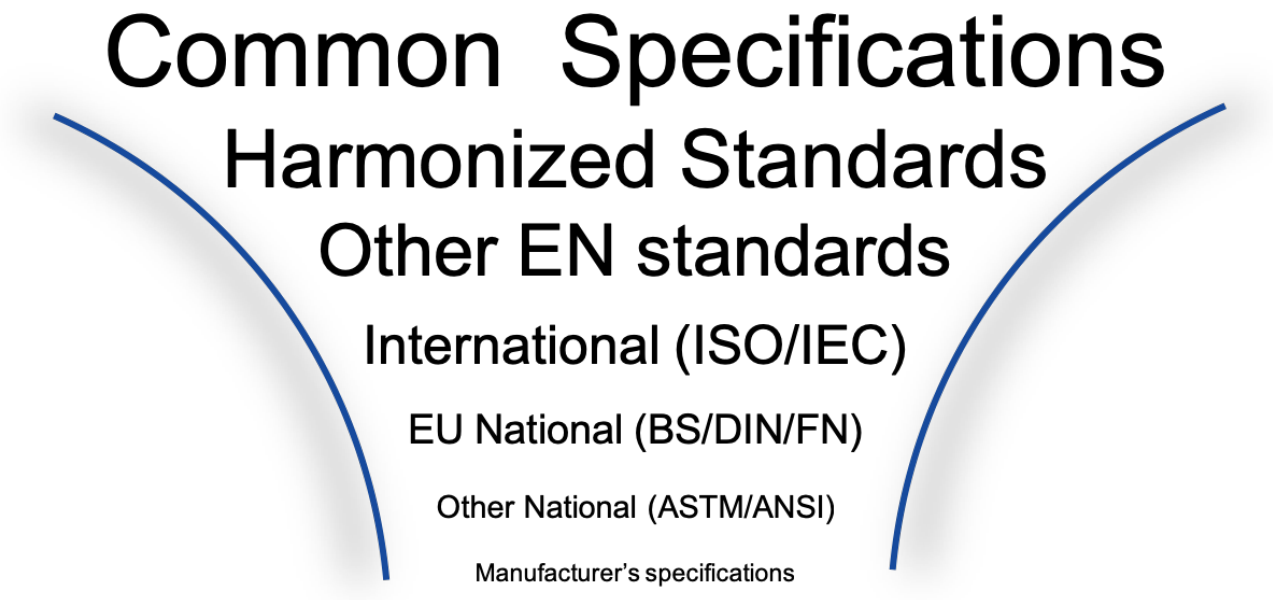
> *'A set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.'*

Common Specifications can be introduced in areas where no harmonised standards exist, where they are insufficient, or where there is a public health threat that needs to be addressed.

Devices that meet the requirements of a Common Specification are presumed to be in conformity with the General Safety and Performance Requirements (GSPRs) of the MDR. Manufacturers must comply with the Common Specification unless they can justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent.

Other Solutions

Other solutions are simply alternative mechanisms (other than compliance to a Common Specification or a Harmonized Standard) that you use to demonstrate conformity with the GSPRs. These can be things such as other International Standards (that aren't harmonised) and a manufacturers own documentation. The MDR specifies a hierarchy with respect to other solutions and what ranking they have in terms of superiority. The following diagram shows this:



Requirement
(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation."

What is the expectation for incorporating a "cross-reference to the location of such evidence within the full technical documentation..."?

This means that someone looking at the document should be able to identify exactly where in the technical documentation that the compliance evidence can be found. For example, this may refer to test reports and their exact location, or it could even reference locations within a large document (depending on the GSPR and your particular documentation. (i.e. if you have included usability risks as part of a larger risk assessment, you may need to say 'See Technical File XXX, Section XX, Doc RMF001 rev 3 lines 65-78'). In other cases it could just mean the whole document reference, i.e. Have you done risk management? – then yes, it is RMF001 rev 3. What the specific reference actually is depends on how you have managed your technical documentation and how defined it is (i.e. separate reports or one big one). There should be no ambiguity as to where the document is located.

An example of a completed GSPR checklist could look something like this (applicable and nonapplicable examples are shown):

GSPR	Description	Applicable?	Methods Applied	Standards & Solutions	Evidence
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	Design considers packaging requirements. Packaged product has been verified through shipping and transit testing. Product was stored at extremes of temperature and humidity.	EN ISO 13485 QMS EN ISO 15223-1 Labelling ISTA 2A Testing	Design procedure XXXXXX, rev XX located in document management system QMS certificate XXXXXXX Package design drawings XXXXXXX, rev XX located in document management system Product label XXXXXXX, rev XX found in section XX of Tech File XX ISTA 2A test report title XXXXX, dated XX/XX/XX found in section XX of Tech FIle XX Storage condition test report title XXXXX, dated XX/XX/XX found in section XX of Tech File XX
11.5	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	No	N/A - This does not apply to this device (device id XXXXX) as it is not a sterile device and cannot be sterilised.	N/A - This does not apply to this device (device id XXXXX) as it is not a sterile device and cannot be sterilised.	N/A - This does not apply to this device (device id XXXXX) as it is not a sterile device and cannot be sterilised.

Proactive Monitoring & Maintenance

Specification developers and manufacturers must continually maintain their technical documentation to stay compliant. Part of this process is to ensure that they take into account the "generally acknowledged state of the art".

Proactive Monitoring

'State of the art'

There is no formal definition of 'sate of the art' within the EU MDR, although it is mentioned 12 times. 'State of the art' is an ongoing debate; however, it generally means that it embodies what is currently and generally accepted as good practice. The 'state of the art' does not necessarily imply the most technologically advanced solution.

This means that if a standard is updated that your medical device is compliant with, you must evaluate that update to ensure that it would meet the EU MDR 'state of the art' requirement. This is not a new requirement from the EU MDD but it is spelled out more clearly in the EU MDR.

The specification developer or manufacturer is ultimately responsible for determining if the updated standard applies or does not apply to their device(s). Either way, the justification should be documented within a gap analysis.

Monitoring for Changes

Of course, 'state of the art' only applies if you actually know if something changed. This is why you need to develop a process for monitoring the standards that compliance is claimed. Every single standard that is associated with your technical documentation must be actively monitored, reviewed, and reported on.

NOTE

If you have product on the market and need a better way to monitor and maintain your General Safety and Performance Requirements (GSPR) or Essential Principles, Rimsys can help. Rrimsys digitizes and automates GSPR and Essential Requirements so you can dynamically update and proactively monitor changing standards and evidence files.

When a standard or evidence file changes, you will automatically be notified and can update one GSPR or all of your GSPRs with a single click of a button. What used to take weeks of manual, error-prone, administrative tasks is now done in seconds within a fully validated, secure, maintenance free, cloud-based solution.

Maintenance

Maintaining your technical documentation is generally the hardest part of staying compliant. Robust processes must be established to ensure nothing slips through the cracks and nonconformances are not identified during regulatory audits.

Gap Analysis

In addition to meeting the 'state of the art' requirements and the continuous proactive monitoring of standards, once a change has been detected that affects the technical documentation, a proper and thorough gap analysis must be completed.

The gap analysis between the old version and the new version, or an evaluation of a brand new standard must occur and be properly documented. The gap analysis should detail what is applicable and what is not applicable, with your supporting justification.

If something within the new or revised standard was considered to be applicable to your device, additional engineering testing, documentation, or justification may be needed to ensure compliance.

GSPR Updates

Once the gap analysis has been properly docuemented, specification developers and manufacturers must update their GSPRs.

These updates includes finding the withdrawn or superseded standard or evidence file throughout each row within your GSPR table, for every single device on the market. This could be one table or dozens of tables depending on the complexity of the products and your product mix.

This is an error-prone process as is it tedious, administrative, and extremely easy to miss an inappropriate referenced standard or evidence file.

Extreme diligence on the regulatory or engineering team must occur to ensure these critical updates to the GSPRs are not missed. The gap analysis must be properly referenced throughout and any justification for including or excluding a new standard or evidence file will be scrutinized by regulatory auditors.

Contributors

James Gianoutsos

Founder & President
Rimsys Inc.

James is a quality assurance and regulatory affairs professional who has a diverse background in the medical device, pharmaceutical and biologics industries. James' professional experience includes the design, premarket approval, clinical trials, manufacturing, distribution and post-market surveillance of drug products and class I, II, and III devices. It also includes products in a variety of clinical applications including infant jaundice management, neonatal respiratory care, infant incubation, sleep therapy, management of respiratory insufficiency, surgical adhesive for internal use, surgical sealant for prevention of gastrointestinal leaks, and bone healing accelerants.

James has extensive experience in establishing and maintaining quality management systems in accordance with FDA, ISO, cGMP, MDD, CMDCAS requirements and standards and has helped develop and submit multiple regulatory filings including Premarket Approvals (PMA), 510(k)s, Design Dossiers, Technical Files and INDs.

James holds a Bachelor of Science in operations management as well as a Master of Business Administration (MBA) with a concentration in operations management and strategy from the University of Pittsburgh – Katz Graduate School of Business.

Rod Beuzeval

Director
Meddev Solutions

Rod has worked in Pharmaceutical and Medical Device sectors for over 19 years and holds a degree in engineering. Rod has earnt Global Regulatory Affairs Certification from the Regulatory Affairs Professional Society.

His expertise lies in providing regulatory guidance to support new product development, worldwide registration and compliance activities. Rod is able to train large groups in the global regulatory requirements as well as QMS.

He has years of hands-on experience of industry standards and regulation such as ISO 13485, ISO 14971, ISO 10993, IEC 60601-1, IEC 62304, IEC 62366, MDD 93/42/EEC, 21CFR, CMDCAS (MDSAP) amongst others.
He has registered devices in over 30 countries including EU, US, Canada, Japan, China, Russia, Kingdom of Saudi Arabia, South Korea and Latin America.

Prior to forming Meddev Solutions, he was a Client Manager for a leading European Notified Body, conducting assessments of QMS for 13485 certification. Rod is still actively engaged with Notified Bodies, performing audits on their behalf and providing technical expertise.

About

Rimsys Regulatory Management Software

Rimsys is a world-leading Regulatory Information Management (RIM) software for medical technology companies that digitizes, automates, and creates regulatory order. The only holistic RIM software for medical devices, in-vitro diagnostics, and medical device software, Rimsys makes it easy to navigate the pillars of regulatory affairs, including product registration, standards management, essential principles/GSPR, and regulatory intelligence. Rimsys is a holistic platform built by and for regulatory affairs professionals to efficiently ensure that products adhere to changing global regulations.

Demo Rimsys Regulatory Management Software

MEDDEV SOLUTIONS

Meddev Solutions are a team of experienced QARA professionals, working in the medical device industry for both manufacturers and notified bodies. Each team member has at least 20 years' experience in the industry and have worked on a wide range of products, from all classes, including implantable, active, software and combination devices.

They routinely train and provide consultancy services to the top medical device manufacturers and have authored the 'MDR Guidebook' to assist manufacturers in complying with the EU MDR. Due to their notified body experience, they can ensure their consultancy delivers solutions that work and courses deliver knowledge that is meaningful. Meddev Solutions are able to support any aspect of compliance to the MDR, through Training, Consultancy, Gap analysis and Audit.

Schedule EU MDR / IVDR Training Now

Appendix 1

Comparison Table (EU MDR Annex I GSPRs vs. EU MDD Annex I Essential Requirements)

EU MDR Annex I General Safety and Performance Requirements	EU MDD Annex I Essential Requirements
Chapter I - General Requirements	**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.	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 intended 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. 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 · 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). 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: · Eliminate or reduce the risks as far as possible (inherently safe design and construction), · Where appropriate, take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, · Inform users of the residual risks due to any shortcomings of the protection methods adopted. 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.
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.	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: · Eliminate or reduce the risks as far as possible (inherently safe design and construction), · Where appropriate, take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, · Inform users of the residual risks due to any shortcomings of the protection methods adopted.
3. Manufacturers shall establish, implement, document and maintain a risk management system.	New GSPR Requirement (although Risk Management was an MDD requirement)
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:	New GSPR Requirement (although Risk Management was an MDD requirement)
(a) establish and document a risk management plan for each device;	New GSPR Requirement (although Risk Management was an MDD requirement)
(b) identify and analyse the known and foreseeable hazards associated with each device;	New GSPR Requirement (although Risk Management was an MDD requirement)
(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;	New GSPR Requirement (although Risk Management was an MDD requirement)

EU MDR Annex I General Safety and Performance Requirements	EU MDD Annex I Essential Requirements
(d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;	New GSPR Requirement (although Risk Management was an MDD requirement)
(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	New GSPR Requirement (although Risk Management was an MDD requirement)
(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.	New GSPR Requirement (although Risk Management was an MDD requirement)
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:	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: · Eliminate or reduce the risks as far as possible (inherently safe design and construction), · Where appropriate, take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, · Inform users of the residual risks due to any shortcomings of the protection methods adopted.
(a) eliminate or reduce risks as far as possible through safe design and manufacture;	
(b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and	
(c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.	
Manufacturers shall inform users of any residual risks.	
5. In eliminating or reducing risks related to use error, the manufacturer shall:	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 intended 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. 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 · 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).
(a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	
(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	
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.	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.
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.	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.

EU MDR Annex I General Safety and Performance Requirements	EU MDD Annex I Essential Requirements
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.	6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended. a) Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.
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.	New Requirement
Chapter II - Requirements regarding design and manufacture	**Chapter II - Requirements regarding design and construction**
10. Chemical, physical and biological properties	7. Chemical, physical and biological properties
10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:	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: · The choice of materials used, particularly as regards toxicity and, where appropriate, flammability, · The compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device, · Where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand. **NOTE - (c), (d), (f), (g) and (h) of GSPR 10.1 are not fully covered by Essential Requirement 7.1**
(a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;	
(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;	
(c) the compatibility between the different parts of a device which consists of more than one implantable part;	
(d) the impact of processes on material properties;	
(e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;	
(f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;	
(g) surface properties; and	
(h) the confirmation that the device meets any defined chemical and/or physical specifications.	
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.	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 the duration and frequency of exposure.
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	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

EU MDR Annex I General Safety and Performance Requirements	EU MDD Annex I Essential Requirements
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.	concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.
10.4. Substances	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. 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 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. **NOTE - Essential Requirement 7.5 does not fully meet the requirements of GSPR 10.4**
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:	
(a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), or	
(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 (2) 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 Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.	
10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances	
The justification for the presence of such substances shall be based upon:	
(a)an analysis and estimation of potential patient or user exposure to the substance;	
(b)an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;	

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(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	
(d)where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.	
10.4.3. Guidelines on phthalates	
For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.	
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.	
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.	
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.	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.
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.	New Requirement
11. Infection and microbial contamination	8. Infection and Microbial Contamination

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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:	8.1 The devices and manufacturing process 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 allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.
(a)reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,	
(b)allow easy and safe handling,	
(c)reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and	
(d)prevent microbial contamination of the device or its content such as specimens or fluids.	
11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	New Requirement
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.	New Requirement, but similar to 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.	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.
11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	8.4 Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.
11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	8.5 Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.
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.	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 contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.
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.	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.
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.	N/A

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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.	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 I of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.
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.	New Requirement
13. Devices incorporating materials of biological origin	N/A

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13.1. For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: (a)donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC; (b)processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process; (c)the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.	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 I of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.
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; (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	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. Processing, preservation, testing and handling of tissues, cells and substance 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.

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transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;	
(c)in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.	
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.	New Requirement
14. Construction of devices and interaction with their environment	9. Construction and Environmental Properties
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.	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 restriction on use must be indicated on the label or in the instructions for use.
14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:	N/A
(a)the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as possible: · The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate ergonomic features. · Risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure acceleration. · The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given. · Risks arising where maintenance or calibration are not possible (as with implants) from aging materials used or loss of accuracy of any measuring or control mechanism.
(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;	
(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;	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.
(d)the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;	New Requirement

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(e)the risks of accidental ingress of substances into the device;	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.
(f)the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and	9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as possible: · The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate ergonomic features. · Risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure acceleration. · The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given. · Risks arising where maintenance or calibration are not possible (as with implants) from aging materials used or loss of accuracy of any measuring or control mechanism.
(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.	
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.	9.3 Devices must be designed & 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.
14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	New Requirement
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.	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 restriction on use must be indicated on the label or in the instructions for use.
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.	10.2 The measurement, monitoring and display scale must be designed in line with ergonomic principles taking into account of the intended purpose of the device.
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.	New Requirement
15. Devices with a diagnostic or measuring function	10. Devices with a Measuring Function
15.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.	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.
15.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (4).	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/IEC, as last amended by Directive 89/617/EEC.
16. Protection against radiation	11. Protection Against Radiation

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16.1. General	11.1 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.	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, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.
(b)The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.	11.4 Instructions 11.4.1 The operating instruction 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 of eliminating the risks inherent in installation.
16.2. Intended radiation	N/A
(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.	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 parameter.
(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.	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.
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.	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 must be reduced as far as possible.
16.4. Ionising radiation	11.5 Ionizing Radiation
(a)Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.	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 account the intended use.
(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.	New Requirement
(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.	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 while minimizing radiation exposure of the patient and user.
(d)Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.	11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a was as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.

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17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves	12 Requirements for Medical Devices Connected to or Equipped with an Energy Source
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.	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. a) 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.
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.	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. a) 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.
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).	New Requirement
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.	New Requirement
18. Active devices and devices connected to them	N/A
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.	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. a) 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.
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.	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.
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.	12.3 Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure.
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.	12.4 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.

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18.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.	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.
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.	New Requirement
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.	12.6 Protection Against Electrical Risks 12.6.1 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.
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.	New Requirement
19. Particular requirements for active implantable devices	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
19.1. Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
(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,	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
(b)risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
(c)risks which may arise where maintenance and calibration are impossible, including:	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
—excessive increase of leakage currents,	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
—ageing of the materials used,	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
—excess heat generated by the device,	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
—decreased accuracy of any measuring or control mechanism.	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
19.2. Active implantable devices shall be designed and manufactured in such a way as to ensure	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
—if applicable, the compatibility of the devices with the substances they are intended to administer, and	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
—the reliability of the source of energy.	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
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.	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
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	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only

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manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.	
20. Protection against mechanical and thermal risks	12.7 Protection Against Mechanical and Thermal Risks
20.1. Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	12.7.1 The device 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.
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.	12.7.2 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generation 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.
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.	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 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.
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.	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 is such a way as to minimize all possible risks.
20.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	New Requirement
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.	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.
21. Protection against the risks posed to the patient or user by devices supplying energy or substances	12.8 Protection against Risks Posed to the Patient by Energy Supplies or Substances
21.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.	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.
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.	12.8.2 Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow rate that could pose a danger.
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	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

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parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.	parameters by means of a visual system, such information must be understandable to the user and, as appropriate, to the patient.
22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	New Requirement
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.	New Requirement
22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to:	New Requirement
—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,	New Requirement
—reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and	New Requirement
—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
22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:	New Requirement
—can verify that, at the time of use, the device will perform as intended by the manufacturer, and	New Requirement
—if applicable, is warned if the device has failed to provide a valid result.	New Requirement
Chapter III - Requirements regarding the information supplied with the device	**13 Information Supplied by the Manufacturer**
23. Label and instructions for use	N/A
23.1. General requirements regarding the information supplied by the manufacturer	N/A
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:	N/A
(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

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(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.	13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instruction for use. 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 the individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. 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 Class IIa if they can be used completely safely without any instructions.
(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.	New Requirement
(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.	13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instruction for use. 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 the individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. 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 Class IIa if they can be used completely safely without any instructions.
(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.	New Requirement
(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.	New Requirement
(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.	New Requirement
(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.	13.2 Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standard exist, the symbols & colors must be described in the documentation supplied with the device.
23.2. Information on the label	N/A
The label shall bear all of the following particulars:	13.3 The label must bear the following particulars:

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(a)the name or trade name of the device;	13.3b) The details strictly necessary to identify the device and the contents of the packaging especially for the users.
(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;	13.3b) The details strictly necessary to identify the device and the contents of the packaging especially for the users. 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.
(c)the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;	13.3a) The name or trade name and address of the manufacturer. 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 where the manufacturer does not have a registered place of business in the Community.
(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;	
(e)where applicable, an indication that the device contains or incorporates:	13.3n) In the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.
—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;	
(f)where applicable, information labelled in accordance with Section 10.4.5.;	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. 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 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.
(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;	13.3d) Where appropriate, the batch code, preceded by the word “LOT” or the serial number.
(h)the UDI carrier referred to in Article 27(4) and Part C of Annex VII;	New Requirement
(i)an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;	13.3e) Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month.

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(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;	13.3l) Year of manufacture of active devices other than those covered by 'e'. This indication may be included in the batch or serial number.
(k)an indication of any special storage and/or handling condition that applies;	13.3i) Any special storage or handling conditions
(l)if the device is supplied sterile, an indication of its sterile state and the sterilisation method;	13.3c) Where appropriate the word "STERILE" 13.3m) Where applicable, method of sterilization
(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;	13.3k) Any warnings and/or precautions to take
(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;	13.3f) Where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community.
(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
(p)if the device is custom-made, the words 'custom-made device';	13.3g) If the device is custom-made, the words "custom-made device"
(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';	13.3h) If the device is intended for clinical investigations, the words "exclusively for clinical investigations"
(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;	New Requirement
(s)for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.	13.3d) Where appropriate, the batch code, preceded by the word "LOT" or the serial number.
23.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging')	N/A
The following particulars shall appear on the sterile packaging:	N/A
(a)an indication permitting the sterile packaging to be recognised as such,	13.3c) Where appropriate the word "STERILE"
(b)a declaration that the device is in a sterile condition,	New Requirement (may be covered by 13.3c)
(c)the method of sterilisation,	13.3m) Where applicable, method of sterilization
(d)the name and address of the manufacturer,	13.3a) The name or trade name and address of the manufacturer. 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 where the manufacturer does not have a registered place of business in the Community.

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(e)a description of the device,	13.3b) The details strictly necessary to identify the device and the contents of the packaging especially for the users.
(f)if the device is intended for clinical investigations, the words 'exclusively for clinical investigations',	13.3h) 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',	13.3g) If the device is custom-made, the words "custom-made device"
(h)the month and year of manufacture,	13.3l) Year of manufacture of active devices other than those covered by 'e'. This indication may be included in the batch or serial number.
(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	13.3e) Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month.
(j)an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.	13.3i) Any special storage or handling conditions
23.4. Information in the instructions for use	N/A
The instructions for use shall contain all of the following particulars:	13.6 Where appropriate, the instructions for use must contain the following particulars:
(a)the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2;	13.6a) The details referred to in Section 13.3 with the exception of d) and e)
(b)the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;	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.
(c)where applicable, a specification of the clinical benefits to be expected.	New Requirement
(d)where applicable, links to the summary of safety and clinical performance referred to in Article 32;	New Requirement
(e)the performance characteristics of the device;	13.6b) The performances referred to in Section 3 and any undesirable side effects.
(f)where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;	New Requirement
(g)any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;	13.6e) Where appropriate, information to avoid certain risks in connection with implantation of the device.
(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;	13.6d) 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. 13.6p) Degree of accuracy claimed for devices with a measuring function.
(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;	13.6i) Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.)

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(j)any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;	13.3j) Any special operating instructions 13.6a) The details referred to in Section 13.3 with the exception of d) and e)
(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:	13.6d) 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.
—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;	
(l)if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;	13.6g) The necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilization.
(m)if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;	13.6h) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfecting, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of 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. 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.
(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;	
(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;	New Requirement
(p)if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request;	13.6h) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfecting, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of 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. 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.
(q)for devices intended for use together with other devices and/or general purpose equipment:	

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—information to identify such devices or equipment, in order to obtain a safe combination, and/or	13.6c) If the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.
—information on any known restrictions to combinations of devices and equipment;	
(r)if the device emits radiation for medical purposes:	13.6j) In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.
—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;	
(s)information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:	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: 13.6k) Precautions to be taken in the event of changes in the performance of the device. 13.6l) 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. 13.6m) 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.
—warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,	
—warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,	
—warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,	
—if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,	
—warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and	
—precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;	
(t)in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose;	New Requirement

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(u)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
(v)warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate:	13.6n) Precautions to be taken against any special unusual risks related to the disposal of the device.
—infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and	New Requirement but under Essential Requirement 13.6n)
—physical hazards such as from sharps.	New Requirement but under Essential Requirement 13.6n)
If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;	New Requirement
(w)for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;	New Requirement
(x)for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;	New Requirement
(y)date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;	13.6q) Date of issue or the latest revision of the instructions for use.
(z)a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;	New Requirement
(aa)information to be supplied to the patient with an implanted device in accordance with Article 18;	New Requirement
(ab)for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.	New Requirement