The ultimate guide to the EU MDR and IVDR General Safety and Performance Requirements (GSPRs)

2nd Edition

Rimsys®

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Overview

Overview

With the initial rollout of the European Medical Device Regulation (MDR) complete, medical device companies are shifting focus to the sister In Vitro Diagnostic Regulation (IVDR) that became effective in May, 2022. Like the MDR, the IVDR also includes new General Safety and Performance Requirements (GSPRs). The expanded 2nd edition of this eBook includes a detailed summary of the IVDR GSPR regulations in addition to those of the MDR. It provides you with practical guidance on how to meet the GSPR requirements for all types of medical technology products.

Timeline

The EU MDR submission became mandatory from the previous MDD directive on May 26, 2021, and the EU IVDR effective date is quickly approaching. In fact, all submissions for new devices under the new EU IVDR had to be implemented no later than May 25, 2022. Below is a high-level overview of key dates for both regulations.

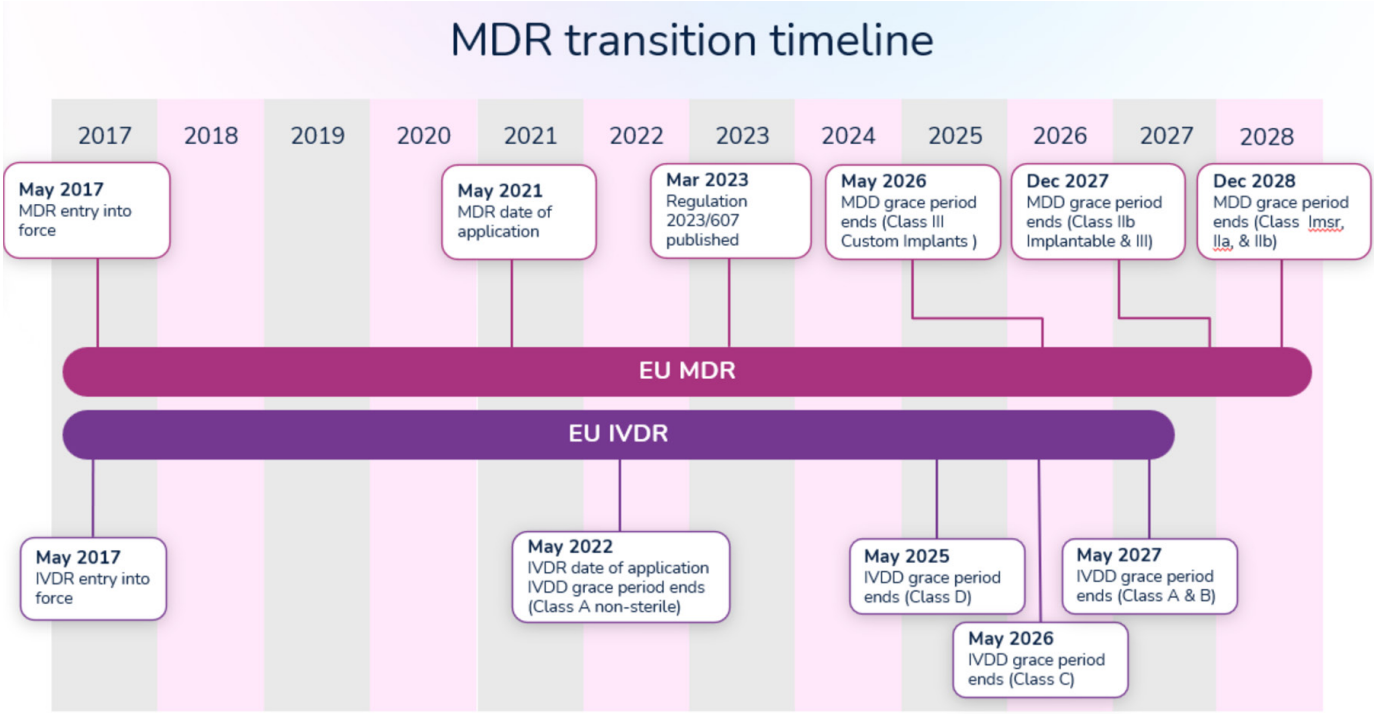


Table 1. EU MDR IVDR timeline including March announced extensions

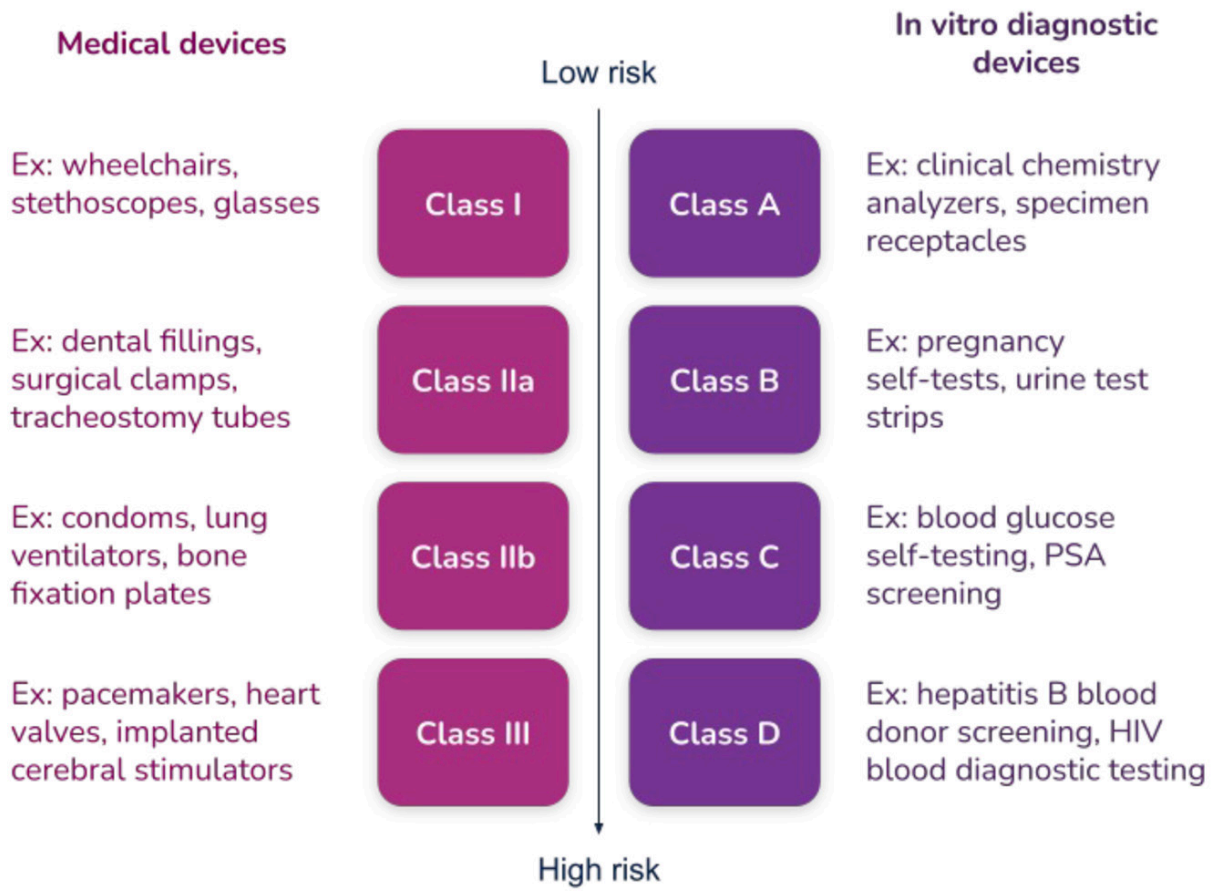


Table 2. EU Classification and Risk factors

Terminology

Terminology

What's the difference between Essential Requirements, Essential Principles, and General Safety and Performance Requirements (GSPR)? Let's discuss the three (3) main terms currently used in the industry.

#1 Essential Requirements

In the previous regulatory framework from the European Union, 'Essential Requirements' was the backbone for establishing conformity with the Medical Device Directive (MDD 93/42/EEC), the Active Implantable Medical Device Directive (AIMDD 90/385/EEC), and the In Vitro Diagnostic Medical Device Directive (IVDs 98/79/EC IVDD). Detailed within Annex I of the MDD, AIMDD, and IVD, the 'Essential Requirements' laid out the requirements that devices must meet to show compliance to those directives. With the implementation of the new EU MDR and IVDR, the 'Essential Requirements' became superseded by the General Safety and Performance Requirements (GSPR).

#2 Essential Principles

The International Medical Device Regulators Forum, also known as IMDRF, laid out Essential Principles requirements in a document titled 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 they were 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 the workflow can overlap many of the Essential Requirements and the EU MDR and IVDR GSPRs.

#3 General Safety and Performance Requirements (GSPR)

As of May 25, 2022, medical device manufacturers that are seeking market access throughout the EU must comply with Annex I - General Safety and Performance Requirements (GSPRs) of the new Medical Device Regulations (MDR 2017/745) and In Vitro Diagnostic Medical Device Regulation (IVDR 2017/746). Note that the GSPR is specific to the European MDR and IVDR, so if you hear any other terms (i.e. Essential Principles), it most likely means it is not referencing the European market or it is possibly being confused with other requirements, GSPR, and other similar terms.

EU MDR/IVDR Annex I

EU MDR/IVDR Annex I

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

The GSPRs are broken down into three (3) chapters in Annex I, MDR 2017/745 and IVDR 2017/746:

- 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 MDR and the IVDR outline General Safety and Performance Requirements (GSPR) in fine detail for medical device designers and manufacturers. The general requirements for each are almost identical 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 risk-benefit ratio.
- Device manufacturers must implement and maintain a thorough, well-documented, and evaluative risk management system that continues to be updated throughout the lifecycle 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.

Refer to the full EU MDR and IVDR text as written in the regulations (MDR 2017/745 and IVDR 2017/746).

Chapter 2 - Requirements regarding design and manufacture

The GSPR also provides key details regarding specific information about the performance, design and manufacture of medical devices. As it relates to design inputs, the MDR and IVDR GSPRs provide highly detailed requirements relating to a device's technical information. Further detail can be found in the comparison tables in Appendix A and Appendix B of this eBook.

Chapter 3 - Requirements regarding the information supplied with the device

The final key area of governance within the GSPR 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 and specific information that must be provided on:

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

Medical device regulation is subject to significant regulation and a full understanding of EU MDR and/or IVDR labeling as defined in Annex 1 Chapter 3 of the regulation.

EU MDR/IVDR Annex II

EU MDR/IVDR Annex II

In addition to the specific requirements identified within Annex I of the EU MDR and IVDR, Annex II, Technical Documentation, identifies additional requirements. Specifically, in both EU MDR and IVDR's Section 4 – General Safety and Performance Requirements it 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 harmonized standards, CS or other solutions applied; and*
> *d. the precise identity of the controlled documents offering evidence of conformity with each harmonized standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross- reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical 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?

Every single section of the EU MDR or IVDR GSPR should be assessed in its own right, as it pertains to your medical device. When a requirement applies, a simple statement can be made that this requirement applies to the device. In practice, this is often achieved using a checklist or table, with a column for applicability and a Yes/No answer against each requirement. When a specific requirement does apply to your device, you will then need to complete 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 fully and properly justified. 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 inapplicable so that your notified body 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 requirement. Historically it would be listed as a standard or

other documentation reference that you used 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 harmonized standards, common specifications, or other solutions applied;

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

Harmonized 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 harmonized. These harmonized standards can only be created by a recognized European Standard Organization (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 harmonized 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.

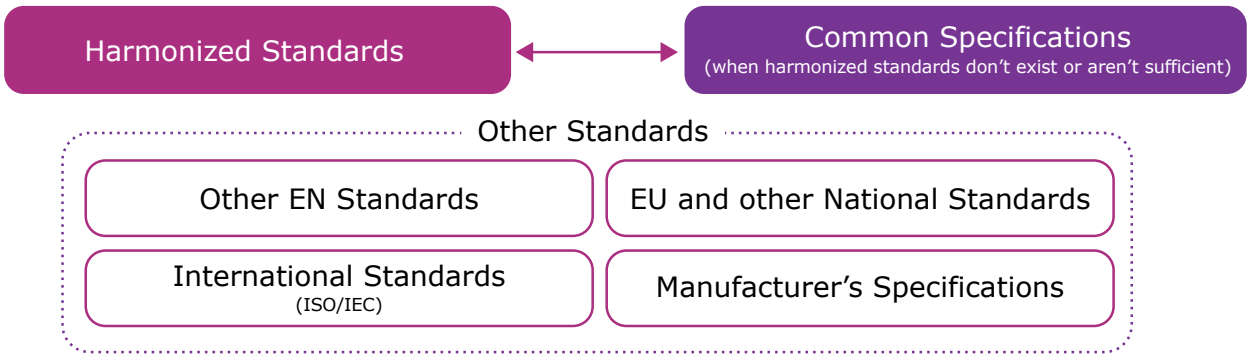
If a standard does not meet a certain requirement of the directive or regulation, or only partially meets it, then you must employ additional mechanisms for compliance. If a harmonized standard meets part of a directive or regulation, then by complying with that standard you also fully meet the corresponding requirement(s). In this case, using an MDD harmonized standard and documenting a justification for doing so (i.e. how you believe the standard demonstrates compliance with the GSPR) should provide sufficient evidence.

Common Specifications

Common Specifications (CS) are a new concept in the MDR and IVDR. They allow the European Union to add additional requirements that must be met to claim compliance. 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."*

Other Solutions is a chosen method of validation chosen and used by the manufacturer, to ensure a level of safety and performance that is at least equivalent to a Common Specification set forth by the EU.



Requirement

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

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 'state of the art' within the EU MDR or IVDR, although it is mentioned many 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 in the medtech industry. 'State of the art' does not necessarily imply the most technologically advanced solution.

One consensus on state of the art is being up-to-date and compliant with the current and in effect standards that are applicable to your device. This means that if a standard is updated that your medical device is compliant with, you must evaluate those changes to ensure that it would meet the EU MDR or EU IVDR 'state of the art' requirement. This is not a new requirement from the EU MDD, but it is spelled out more clearly in the new regulations.

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 know that a standard has changed. This is why you need to develop a process for monitoring the standards that your medtech device has claimed compliance. Every single standard that is associated with your technical documentation must be actively monitored, reviewed, and reported on.

Note - If you have a 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. Rimsys can digitize and automate GSPR and Essential Requirements so you can easily update and proactively monitor changing standards and evidence files quickly.

Within Rimsys, when a standard or evidence file changes, you will automatically be notified, and then you can update one GSPR or all of your GSPRs, as applicable, with a single click of a button. If additional information is needed, such as testing, it's also invaluable to ensure that all devices are identified. 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 and updating your technical documentation is generally the hardest part of staying compliant. Robust processes must be established to ensure nothing slips through the cracks and show up as nonconformances 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 versions and the new versions, 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 applicable to your device, additional engineering testing, documentation, justification, and in some instances design changes, may be needed to ensure you remain compliant.

GSPR updates

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

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

Without a holistic RIM system to help you, this is an error-prone process as it is 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 GSPR are not missed, and the gap analysis must be properly referenced throughout. Any justification for including or excluding a new standard or evidence file will be scrutinized by regulatory auditors and without proper maintenance, may lead to additional review time.

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Appendix A: Comparison table (EU MDR Annex I GSPRs vs EU MDD Annex I Essential Principles)

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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)

EU MDR Annex I General Safety and Performance Requirements	EU MDD Annex I Essential Requirements
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)
(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.

EU MDR Annex I General Safety and Performance Requirements	EU MDD Annex I Essential Requirements
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.
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 GSPR 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 may cause additional requirements as they 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 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.	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.

EU MDR Annex I General Safety and Performance Requirements	EU MDD Annex I Essential Requirements
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;	
(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	

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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 GSPR requirement
11. Infection and microbial contamination	8. Infection and Microbial Contamination
11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:	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 GSPR 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 GSPR 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.

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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
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

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	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 GSPR requirement
13. Devices incorporating materials of biological origin	N/A
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:	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
(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.	

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	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:	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.
(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 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 GSPR 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;	

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(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 GSPR requirement
(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 (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.	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.
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 GSPR 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 GSPR 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.

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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
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 GSPR 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.
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

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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 GSPR 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 GSPR 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.
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 GSPR requirement

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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 GSPR 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 manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.	N/A - No Essential Requirement in 93/42/EEC Applicable to AIMDD Only
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.

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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 minimize 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.	New GSPR requirement
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.	
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 parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.	12.9. The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, to the patient.
22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	New GSPR 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 GSPR requirement
22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to:	New GSPR 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 GSPR requirement
—reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and	New GSPR 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 GSPR requirement
22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:	New GSPR requirement
—can verify that, at the time of use, the device will perform as intended by the manufacturer, and	New GSPR requirement
—if applicable, is warned if the device has failed to provide a valid result.	New GSPR requirement

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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 GSPR requirement
(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 GSPR 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 GSPR requirement

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(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 GSPR 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 GSPR 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:
(a) the name or trade name of the device;	13.3. b) 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;	13.3. b) 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 trademark of the manufacturer and the address of its registered place of business;	13.3. a) 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:	13.3. n) 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

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	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;	13.3. d) 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 GSPR 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;	13.3. e) Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month.
(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;	13.3. l) 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;	13.3. i) Any special storage or handling conditions
(l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method;	13.3. c) Where appropriate the word "STERILE" 13.3. m) 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;	13.3. k) 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;	13.3. f) Where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community.
(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 GSPR requirement
(p) if the device is custom-made, the words 'custom-made device';	13.3. g) 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';	13.3. h) 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 GSPR requirement
(s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.	13.3. d) 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,	13.3. c) Where appropriate the word "STERILE"
(b) a declaration that the device is in a sterile condition,	New GSPR requirement (may be covered by 13.3 c)

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(c) the method of sterilisation,	13.3. m) Where applicable, method of sterilization
(d) the name and address of the manufacturer,	13.3. a) 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.
(e) a description of the device,	13.3. b) 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',	13.3. h) 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',	13.3. g) If the device is custom-made, the words "custom-made device"
(h) the month and year of manufacture,	13.3. l) 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	13.3. e)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.	13.3. i) 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;	13.6. a) 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 GSPR requirement
(d) where applicable, links to the summary of safety and clinical performance referred to in Article 32;	New GSPR requirement
(e) the performance characteristics of the device;	13.6. b) 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 GSPR requirement
(g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;	13.6. e) 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;	13.6. d) All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times. 13.6. p) Degree of accuracy claimed for devices with a measuring function.

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(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;	13.6. i) Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.)
(j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;	13.6. j) Any special operating instructions 13.6. a) 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:	13.6. d) All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times.
—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;	13.6. g) 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;	13.6. h) 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 GSPR 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;	13.6. h) 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.

EU MDR Annex I General Safety and Performance Requirements	EU MDD Annex I Essential Requirements
(q) for devices intended for use together with other devices and/or general purpose equipment:	13.6. c) 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 to identify such devices or equipment, in order to obtain a safe combination, and/or	
—information on any known restrictions to combinations of devices and equipment;	
(r) if the device emits radiation for medical purposes:	13.6. j) 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: 13.6. k) Precautions to be taken in the event of changes in the performance of the device. 13.6. l) Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.
—warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,	13.6. m) Adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered.
—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 GSPR requirement
(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 GSPR requirement

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(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:	13.6. n) 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 GSPR requirement but under Essential Requirement 13.6 n)
—physical hazards such as from sharps.	New GSPR requirement but under Essential Requirement 13.6 n)
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 GSPR requirement
(w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;	New GSPR 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 GSPR 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;	13.6. q) 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 GSPR requirement
(aa) information to be supplied to the patient with an implanted device in accordance with Article 18;	New GSPR 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 GSPR requirement

Appendix B: Comparison table (EU IVDR Annex I GSPRs vs EU IVDD Annex I Essential Principles)

Appendix B: Comparison table (EU IVDR Annex I GSPRs vs EU IVDD Annex I Essential Principles)

EU IVDR Annex I General Safety and Performance Requirements	EU IVDD Annex I Essential Requirements
Chapter I - General requirements	**A. 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.	A.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, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.
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.	New GSPR requirement
3. Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:	New GSPR requirement
(a) Establish and document a risk management plan for each device;	New GSPR requirement
(b) Identify and analyse the known and foreseeable hazards associated with each device;	New GSPR requirement
(c) Estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;	New GSPR requirement
(d) Eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;	New GSPR 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, the benefit-risk ratio and risk acceptability; and	New GSPR 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
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, the manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:	A.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...
(a) Eliminate or reduce risks as far as possible through safe design and manufacture;	• ...eliminate or reduce risks as far as possible (inherently safe design and construction) ...
(b) Where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and	• ...where appropriate take adequate protection measures in relation to risks that cannot be eliminated...
(c) Provide information for safety (warnings/precautions/ contra-indications) and, where appropriate, training to users.	New GSPR requirement
Manufacturers shall inform users of any residual risks.	• ...inform users of the residual risks due to any shortcomings of the protection measures adopted...

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5. In eliminating or reducing risks related to use error, the manufacturer shall:	New GSPR requirement
(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	New GSPR requirement
(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).	New GSPR requirement
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.	A.4. The characteristics and performances referred to in sections 1 and 3 must not be adversely affected to such a degree that the health or the 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. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.
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.	A.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 under storage and transport conditions (temperature, humidity, etc.) taking account of the instructions and information provided by the manufacturer.
8. All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal conditions of use.	New GSPR requirement
Chapter II - Requirements regarding performance, design, and manufacturing	**A. Design and manufacturing requirements**
9. Performance characteristics	
9.1. Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable;	A.3. The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 1(2)(b), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer. The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.
(a) The analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross- reactions; and	Under Essential Requirements A.3.
(b) The clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.	Under Essential Requirements A.3.
9.2. The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.	New GSPR requirement

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9.3. Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.	Under Essential Requirements A.3.
9.4. The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions:	New GSPR requirement
(a) For devices for self-testing, performances obtained by laypersons;	New GSPR requirement
(b) For devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).	New GSPR requirement
10. Chemical, physical, and biological properties	B.1. Chemical and physical 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 the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.	B.1.1. The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in section A on the 'General requirements`. Particular attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens (such as biological tissues, cells, body fluids and micro- organisms) intended to be used with the device, taking account of its intended purpose.
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.	B.1.2. The devices must be designed, manufactured and packed in such a way as to reduce as far as possible the risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the products.
10.3. Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified 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).	New GSPR requirement
10.4. 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.	New GSPR requirement
11. Infection and microbial contamination	B.2. Infection and microbial contamination
11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons. The design shall:	B.2.1. The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design... The manufacturing processes must be appropriate for these purposes.
(a) Allow easy and safe handling;	...must allow easy handling...
(b) Reduce as far as possible any microbial leakage from the device and/or microbial exposure during use;	...and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use...
(c) And, where necessary Prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.	...and, in the case of specimen receptacles, the risk of contamination of the specimen...

EU IVDR Annex I General Safety and Performance Requirements	EU IVDD Annex I Essential Requirements
11.2. Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.	B.2.3. Devices labeled either as 'STERILE' or as having a special microbiological state must be designed, manufactured and packed in an appropriate pack, according to procedures suitable for ensuring that they remain in the appropriate microbiological state indicated on the label when placed on the market, under the storage and transport conditions specified by the manufacturer, until the protective packaging is damaged or opened.
11.3. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	B.2.4. Devices labeled either as 'STERILE' or as having a special microbiological state must have been processed by an appropriate, validated method.
11.4. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	B.2.6. Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.
11.5. 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.	B.2.7. 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 sterilised prior to use, minimise the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.
11.6. 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.	New GSPR requirement
12. Devices incorporating materials of biologic origin	
Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person.	B.2.2. Where a device incorporates biological substances, the risks of infection must be reduced as far as possible by selecting appropriate donors and appropriate substances and by using appropriate, validated inactivation, conservation, test and control procedures.
13. Construction of devices and interaction with their environment	B.3. Manufacturing and environmental properties
13.1. 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 performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.	B.3.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated onthe label and/or in the instructions for use.
13.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:	B.3.3. Devices must be designed and manufactured in such a way as to remove or reduce as far as possible...
(a) The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	• ...the risk of injury linked to their physical features (in particular aspects of volume x pressure, dimension and, where appropriate, ergonomic features)...
(b) Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;	• ...risks linked to reasonably foreseeable external influences, such as magnetic fields, external electrical effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure or acceleration or accidental penetration of substances into the device.
(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;	B.3.2. Devices must be designed and manufactured in such a way as to reduce as far as possible the risks linked to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use.
(d) The risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;	New GSPR requirement
e) The risks of accidental ingress of substances into the device;	New GSPR requirement
(f) The risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/ or numeric and/or character codings on specimen receptacles, removable parts and/ or accessories used with devices in order to perform the test or assay as intended;	New GSPR requirement

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(g) The risks of any foreseeable interference with other devices.	New GSPR requirement
13.3. 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.	B.3.4. Devices must be designed and manufactured in such a way as to reduce as far as possible 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 or use in association with flammable substances or substances which could cause combustion.
13.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	New GSPR requirement
13.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	New GSPR requirement
13.6. 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 users, 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.	B.3.5. Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.
13.7. The measuring, monitoring or display scale (including colour change and other visual indicators) 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.	B.3.6. The measuring, monitoring or display scale (including colour change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.
14. Devices with a measuring function	B.4. Devices which are instruments or apparatus with a measuring function
14.1. Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended purpose of the device.	B.4.1. Devices which are instruments or apparatus having a primary analytical measuring function must be designed and manufactured in such a way as to provide adequate stability and accuracy of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer.
14.2. 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 (3).	B.4.2. When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement.
15. Protection against radiation	B.5. Protection against radiation
15.1. Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) 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 diagnostic purposes.	B.5.1. Devices shall be designed, manufactured and packaged in such a way that exposure of users and other persons to the emitted radiation is minimised.
15.2. When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be:	B.5.2. When devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be...
(a) Designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and	• ...designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted...
(b) Fitted with visual displays and/or audible warnings of such emissions.	• ...fitted with visual displays and/or audible warnings of such emissions.
15.2. 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 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.	B.5.3. The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.

EU IVDR Annex I General Safety and Performance Requirements	EU IVDD Annex I Essential Requirements
16. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves	
16.1. 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.	B.6.1. Devices incorporating electronic programmable systems, including software, must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.
16.2. 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.	New GSPR requirement
16.3. 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 GSPR requirement
16.4. 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 GSPR requirement
17. Devices connected to or equipped with an energy source	B.6. Requirements for medical devices connected to or equipped with an energy source
17.1. For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.	New GSPR requirement
17.2. For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.	New GSPR requirement
17.3. 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.	B.6.2. Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic perturbation which could impair the operation of other devices or equipment in the usual environment.
17.4. 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 GSPR requirement
17.5. 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 user, or 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.	B.6.3. 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 and maintained correctly.
18. Protection against mechanical and thermal risks	B.6.4. Protection against mechanical and thermal risks
18.1. 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 and maintained correctly.	B.6.4.1. Devices must be designed and manufactured in such a way as to protect the user against mechanical risks...
18.2. Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer. Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.	Devices must be sufficiently stable under the foreseen operating conditions. They must be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected life of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer. Any guards or other means included with the device to provide protection, in particular against moving parts, must be secure and must not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.

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18.3. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated.
18.4. 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.	B.6.4.2. Devices must 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.
18.5. 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.	B.6.4.3. Devices must be designed and manufactured in such a way as to reduce as far as possible 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.
18.6. 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.	B.6.4.4. Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimise all possible risks.
18.7. 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 GSPR requirement
18.8. 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.	B.6.4.5. Accessible parts of the devices (excluding the parts of areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.
19. Protection against the risks posed by devices intended for self-testing or near-patient testing	B.7. Requirements for devices for self-testing
19.1. Devices intended for self-testing or near-patient testing 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 the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.	Devices for self-testing must 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 users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.
19.2. Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to:	B.7.1. Devices for self-testing must be designed and manufactured in such a way as to...
(a) Ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/ or information; and	• ...ensure that the device is easy to use by the intended lay user at all stages of the procedure, and...
(b) Reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.	• ...reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results
19.3. Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user:	B.7.2. Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure...
(a) Can verify that, at the time of use, the device will perform as intended by the manufacturer; and	...by which the user can verify that, at the time of use, the product will perform as intended.
(b) Be warned if the device has failed to provide a valid result.	New GSPR requirement

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Chapter III - Requirements regarding information supplied with the device	**B.8. Information supplied by the manufacturer**
20. Labeling and instructions for use	
20.1. General requirements regarding the information supplied by the manufacturer Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:	B.8.1. Each device must be accompanied by the information needed to use it safely and properly... and to identify the manufacturer. This information comprises the data on the label and in the instructions for use.
(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.	...taking account of the training and knowledge of the potential users...
(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. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.	As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labeling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices. Instructions for use must accompany or be included in the packaging of one or more devices.
(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes.	New GSPR requirement
(d) Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.	Instructions for use must accompany or be included in the packaging of one or more devices. In duly justified and exceptional cases no such instructions for use are needed for a device if it can be used properly and safely without them.
(e) Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, 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 GSPR requirement
(f) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.	New GSPR 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 GSPR requirement
(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols, taking into account the intended users. 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.	B.8.2. Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device.

EU IVDR Annex I General Safety and Performance Requirements	EU IVDD Annex I Essential Requirements
(i) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labeling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.	B.8.3. In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labeling requirements of Directive 67/548/EEC (2) and Directive 88/379/EEC (3) shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use.
(j) The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information, as appropriate, is already made available in the instructions for use.	New GSPR requirement
20.2. Information on the label The label shall bear all of the following particulars:	B.8.4. The label must bear the following particulars which may take the form of symbols as appropriate...
(a) The name or trade name of the device;	(a) The name or trade name...
(b) The details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;	(b) The details strictly necessary for the user to uniquely identify the device and the contents of the packaging; B.8.5. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label.
(c) The name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;	B.8.4. (a) The name or trade name and address of the manufacturer...
(d) If the manufacturer has its registered place of business outside the Union, the name of its authorised representative and the address of the registered place of business of the authorised representative;	...For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative of the manufacturer;
(e) An indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;	(f) In case of devices for performance evaluation, the words 'for performance evaluation only'; (g) Where appropriate, a statement indicating the in vitro use of the device;
(f) 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;	(d) The batch code, preceded by the word 'LOT`, or the serial number;
(g) The UDI carrier as referred to in Article 24 and Part C of Annex VI;	New GSPR requirement
(h) An unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;	B.8.4. (e) If necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order;
(i) 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;	New GSPR requirement
(j) Where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;	New GSPR requirement
(k) An indication of any special storage and/or handling condition that applies;	B.8.4. (h) Any particular storage and/or handling conditions;
(l) Where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;	(c) Where appropriate, the word 'STERILE` or a statement indicating any special microbiological state or state of cleanliness;
(m) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or 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;	(j) Appropriate warnings and/or precautions to take;

EU IVDR Annex I General Safety and Performance Requirements	EU IVDD Annex I Essential Requirements
(n) If the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their accessibility (or availability), and where applicable the website address where they can be consulted;	New GSPR requirement
(o) Where applicable, any particular operating instructions;	B.8.4. (i) Where applicable, any particular operating instructions;
(p) 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;	New GSPR requirement
(q) If the device is intended for self-testing or near-patient testing, an indication of that fact;	B.8.4. (k) If the device is intended for self-testing, that fact must be clearly stated.
(r) Where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;	New GSPR requirement
(s) Where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;	New GSPR requirement
(t) The devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. As far as practicable and appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;	B.8.6. Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.
(u) The label for devices for self-testing shall bear the following particulars:	New GSPR requirement
(u)(i) The type of specimen(s) required to perform the test (e.g. blood, urine or saliva);	New GSPR requirement
(u)(ii) The need for additional materials for the test to function properly;	New GSPR requirement
(u)(iii) Contact details for further advice and assistance.	New GSPR requirement
(u) The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.	New GSPR requirement
20.3. Information on the packaging which maintains the sterile condition of a device('sterile packaging') The following particulars shall appear on the sterile packaging:	New GSPR requirement
(a) An indication permitting the sterile packaging to be recognised as such,	New GSPR requirement
(b) A declaration that the device is in a sterile condition,	New GSPR requirement
(c) The method of sterilisation,	New GSPR requirement
(d) The name and address of the manufacturer,	New GSPR requirement
e) A description of the device,	New GSPR requirement
(f) The month and year of manufacture,	New GSPR requirement
(g) An unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order,	New GSPR requirement
(h) An instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.	New GSPR requirement
20.4. Information in the instructions for use	
20.4.1. The instructions for use shall contain all of the following particulars:	B.8.7. Where appropriate, the instructions for use must contain the following particulars… the details referred to in section 8.4 with the exception of points (d) and (e);

EU IVDR Annex I General Safety and Performance Requirements	EU IVDD Annex I Essential Requirements
(a) The name or trade name of the device;	B.8.4. (a) The name or trade name and address of the manufacturer…
(b) The details strictly necessary for the user to uniquely identify the device;	B.8.4. (b) The details strictly necessary for the user to uniquely identify the device and the contents of the packaging;
(c) The device's intended purpose:	B.8.5. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label.
(c)(i) What is detected and/or measured;	New GSPR requirement
(c)(ii) Its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);	New GSPR requirement
(c)(iii) The specific information that is intended to be provided in the context of:	New GSPR requirement
—a physiological or pathological state;	
—congenital physical or mental impairments;	
—the predisposition to a medical condition or a disease;	
—the determination of the safety and compatibility with potential recipients;	
—the prediction of treatment response or reactions;	
—the definition or monitoring of therapeutic measures;	
(c)(iv) Whether it is automated or not;	New GSPR requirement
(c)(v) Whether it is qualitative, semi-quantitative or quantitative;	New GSPR requirement
(c)(vi) The type of specimen(s) required;	B.8.7. (f) The type of specimen to be used…
(c)(vii) Where applicable, the testing population; and	New GSPR requirement
(c)(viii) For companion diagnostics, the International Non- proprietary Name (INN) of the associated medicinal product for which it is a companion test.	New GSPR requirement
(d) An indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;	B.8.4. (f) In case of devices for performance evaluation, the words 'for performance evaluation only'; (g) Where appropriate, a statement indicating the in vitro use of the device
(e) The intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);	New GSPR requirement
(f) The test principle;	B.8.7. (h) The measurement procedure to be followed with the device including as appropriate…the principle of the method…
(g) A description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);	New GSPR requirement
(h) A description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	B.8.7. (b) Composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;
(i) A list of materials provided and a list of special materials required but not provided;	(e) An indication of any special equipment required including information necessary for the identification of that special equipment for proper use;

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(j) For devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment:	B.8.7. (m) If the device must be used in combination with or 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 and proper combination;
—information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance	
—information on any known restrictions to combinations of devices and equipment.	
(k) An indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;	B.8.4. (h) Any particular storage and/or handling conditions;
(l) In-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;	B.8.7. (c) The storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working reagents;
(m) If the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;	
(n) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate:	B.8.4. (j) Appropriate warnings and/or precautions to take;
(n)(i) Warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,	New GSPR requirement
(n)(ii) 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,	B.8.7. (r) 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.;
(n)(iii) 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, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,	New GSPR requirement
(n)(iv) 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,	New GSPR requirement
(n)(v) 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,	New GSPR requirement
(n)(vi) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re- sterilisation. Information shall be provided to identify when the device should no longer be reused, such as signs of material degradation or the maximum number of allowable reuses;	B.8.7. (q) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilisation or decontamination, and any restriction on the number of reuses;
(o) Any warnings and/or precautions related to potentially infectious material that is included in the device;	New GSPR requirement
(p) Where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on radiation safety, or particular qualifications of the intended user;	New GSPR requirement
(q) Conditions for collection, handling, and preparation of the specimen;	B.8.7. (f) ...any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;
(r) Details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final assembly, calibration, etc., for the device to be used as intended by the manufacturer;	(o) Details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.)

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(s) 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:	B.8.7. (n) 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 device operates properly and safely; information about safe waste disposal;
—details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;	
—identification of any consumable components and how to replace them;	
—information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;	
—methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.	
(t) Where applicable, recommendations for quality control procedures;	B.8.7. (k) • Information appropriate to users on... internal quality control including specific validation procedures,
(u) The metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;	• Information appropriate to users on...the traceability of the calibration of the device;
(v) Assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant	B.8.7. • (g) A detailed description of the procedure to be followed in using the device;
(w) Analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;	B.8.7. (h) • ...the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences), limitations of the method and information about the use of available reference measurement procedures and materials by the user...
(x) Clinical performance characteristics as defined in Section 9.1 of this Annex;	B.8.7. (d) The performances referred to in section 3 of part A; (see IVDR Section 9)
(y) The mathematical approach upon which the calculation of the analytical result is made;	B.8.7. (i) The mathematical approach upon which the calculation of the analytical result is made;
(z) Where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;	B.8.7. (d) The performances referred to in section 3 of part A; (see IVDR Section 9)
(aa) Where relevant, reference intervals in normal and affected populations;	B.8.7. (i) The reference intervals for the quantities being determined, including a description of the appropriate reference population;
(ab) Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;	New GSPR requirement
(ac) 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:	B.8.7. (s) Precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature;
(ac)(i) Infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;	New GSPR requirement

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(ac)(ii) Environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);	New GSPR requirement
(ac)(iii) Physical hazards such as explosion.	New GSPR requirement
(ad) The name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;	B.8.4. (a) The name or trade name and address of the manufacturer...
(ae) 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, with a clear indication of the introduced modifications;	B.8.7. (u) Date of issue or latest revision of the instructions for use.
(af) A notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established;	New GSPR requirement
(ag) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation;	New GSPR requirement
(ah) 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 GSPR requirement
20.4.2. In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles:	B.8.7. (t) Specifications for devices for self-testing
(a) Details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;	New GSPR requirement
(b) Specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;	B.8.7. (t) • Specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device,
(c) The device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;	New GSPR requirement
(d) The results shall be expressed and presented in a way that is readily understood by the intended user;	B.8.7. (t) • The results need to be expressed and presented in a way that is readily understood by a lay person;
(e) Information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;	• ...information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result
(f) The information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice such as national helplines, websites;	• The information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner,
(g) For devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.	• The information must also specify that when the device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so;

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