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A BSI white paper

Symbols and information to be provided with medical devices and IVDs in the EU

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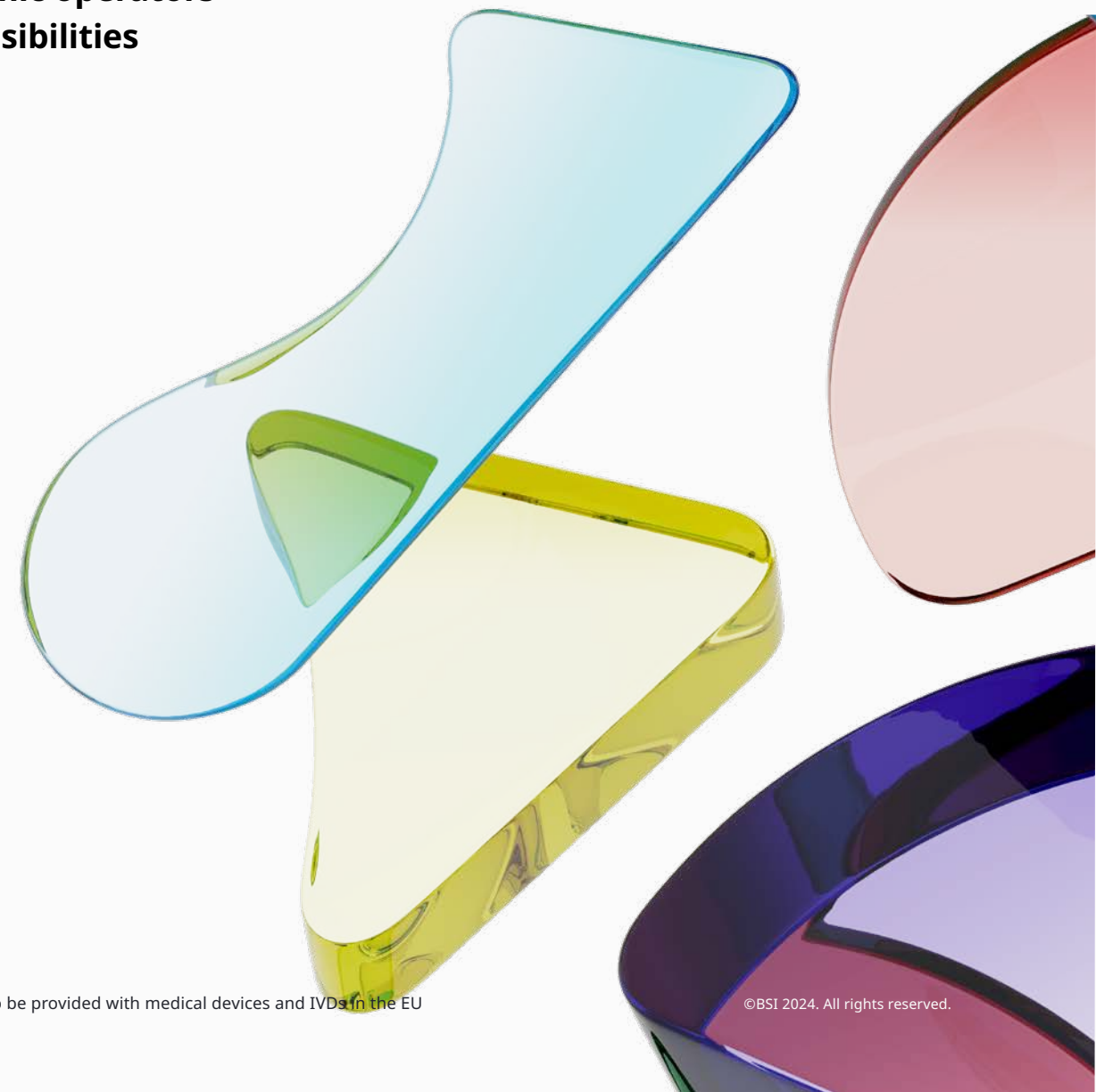

Introduction and background

The information supplied with the device is a fundamental requirement for the safe use of a medical/in vitro diagnostic device.

The instructions for use (IFU) are crucial as they inform the user of a device's intended purpose and of its proper use, as well as any precautions to be taken. Being aimed at ensuring that the devices are used in a safe and effective way, it is vital that the information provided is adequate for the device itself.

The label is defined in the Regulations as the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices. Therefore, it can assume not only the form of a text, but also that of a graphic and/or, of a symbol.

The labeling includes the implant card, to be provided to patients who have been implanted with a device. This allows rapid access to information related to the identification of the device itself as well as details on the manufacturer.

The information supplied with the device is checked by Notified Bodies for accuracy to ensure its content is in compliance with the requirements of the Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), safeguarding the quality and safety of devices placed on the market.

General safety and performance requirements (GSPRs)

Compliance with the GSPRs is the basis for establishing conformity with the MDR and the IVDR.

GSPR 23.1 of the MDR (GSPR 20.1 of the IVDR) provides the general requirements regarding label and instructions for use, but other GSPRs as well as other articles of the Regulations provide further detailed requisites.

Annex II of the MDR/IVDR specifies that labels and instructions for use shall be clearly organized, easy to find, and free from any ambiguity when presented in the device's technical documentation.

Article 7 of the MDR/IVDR states that it's not allowed to use text, names, trademarks, pictures, or any signs that could deceive the user or patient about what the device is intended for, how safe it is, or how it performs.

Specifics related to the implant card are listed in Article 18 of the MDR.

GSPRs impacting labeling and information to be provided with medical devices and in-vitro diagnostic devices are numerous, covering, as applicable:

- Transport and storage.
- Compatibility with materials and substances.
- Carcinogenic, mutagenic, or toxic to reproduction substances and substances with endocrine-disrupting properties.
- Sterilisation and microbial state.
- Reuse.
- Devices incorporating materials of biological origin.
- Environment and device compatibility, including device disposal.
- Devices with a diagnostic or measuring function.
- Protection against radiation, against mechanical and thermal risks, against the risks posed to the patient or user by devices supplying energy or substances.
- Devices that incorporate electronic programmable systems and software that are devices in themselves.
- Active devices and devices connected to them (including active implantable devices).
- Devices intended by the manufacturer for use by lay persons.
- Details of requirements are provided in the next chapters of this whitepaper.

BSI has previously published a previous whitepaper on "**Phthalates and endocrine disruptors**", which provides an overview of their safety requirements and evaluations together with the standards that support them.

Transport and storage	**Sterilisation and microbial state**	**Reuse**
Compatibility with materials and substances	**CMR substances and ED**	**Materials of biological origin**
Diagnostic or measuring function	**Electronic programmable systems and software**	**Active devices and devices connected to them**
Devices intended for use by lay persons	**Radiation, mechanical and thermal risks, devices supplying energy or substances**	**Environment and device compatibility**

General requirements as per GSPR 23.1 (MDR)/GSPR 20.1 (IVDR) for label and IFU

What to include

Identification of the device and its relevant economic operators.

Identification of any safety and performance information relevant to the user, or any other person, as appropriate.

Residual risks to be included as limitations, contraindications, precautions or warnings.

IVD: hazard pictograms and labeling requirements of Regulation (EC) No 1272/2008.

CE marking.

Where to be placed

The information required on the **label** shall be provided on the device itself, unless it is not practicable or appropriate.

For sterile devices, specific information is required on the packaging which maintains the sterile condition.

IVDs hazard pictograms and labeling requirements of Regulation (EC) No 1272/2008 shall be put on the device itself or on the label, unless there is not sufficient space.

Instructions for use shall be provided together with devices.

Exceptions for certain Class I and Class IIa medical devices and for certain IVDs.

Exception for multiple devices supplied to a single user and/or location (unless they are IVDs intended for self-testing or near-patient testing).

How to provide the information

Labels: human-readable format and may be supplemented by machine-readable information.

Instructions for use: paper format. It may be electronic in some specific instances.

Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized symbols.

Identification of the device, its manufacturer, any safety and performance information relevant to the user, or any other person is to be made available and kept up to date on the manufacturer's website.

For whom (intended user)

Appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s).

Instructions for use to be written in terms readily understood by the intended user.

What to include on the label and IFU

The Regulations are clear about the content of the labeling.

In the first place, there is a need to guarantee the traceability of the device (including device name, lot number or the serial number, Unique Device Identifier - UDI) and of the relevant economic operators.

Secondly, any safety and performance information relevant to the user, or any other person, as appropriate, as well as any residual risk (to be included as limitations, contra-indications, precautions or warnings) shall be identified and disclosed.

For in-vitro diagnostic devices (IVD), these include relevant hazard pictograms and labeling requirements of Regulation (EC) No 1272/2008[1] in 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. Moreover, the provisions of Regulation (EC) No 1907/2006[2] on the safety data sheet shall apply, unless all relevant information, as appropriate, is already made available in the instructions for use.

Ultimately, article 20 of the MDR (article 18 of the IVDR) provides the requirements for affixing of the CE marking to the device or to its sterile packaging, or, in particular cases, to any further packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Where to place the label and instructions for use

When practicable or appropriate, the information required on the label shall be provided on the device itself. If this is not the case, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

Packaging ensuring the sterile condition of a device shall be labeled with all the applicable information listed in GSPR 23.3 (MDR)/GSPR 20.3 (IVDR).

IVDs relevant hazard pictograms and labeling requirements of Regulation (EC) No 1272/2008 shall be put on the device itself or on the label, unless there is no sufficient space, in which case it is allowed to provide the relevant hazard pictograms on the label and the other information in the IFU.

Instructions for use shall be provided with the devices. Exceptions apply to Class I and Class IIa medical devices that can be used safely without any such instructions.

For these devices it is acceptable that no instructions for use are supplied with the device unless otherwise provided for elsewhere in the MDR. For those devices that do not require an instruction for use, any residual risks relevant to the user and/or other person needs to be provided on the labeling.

Parallelly, in case of justified and exceptional cases, IFUs shall not be required or may be abbreviated if an IVD can be used safely and as intended by the manufacturer without any instructions for use.

Furthermore, there might be multiple medical devices supplied to a single user and/or location. In this case, a single copy of the instructions for use may be provided in agreement with the purchaser who has the right to request further copies free of charge. The same applies to IVDs except for devices intended for self-testing or near-patient testing.

How to provide the information for use

The instructions for use are mainly to be provided in a paper format, but the MDR and the IVDR foresee the use of electronic IFUs (e-IFU) when allowed by the Regulation (EU) 2021/2226[3] (for medical devices) and in case of IVDs intended for professional use only, except when the device is intended for near-patient testing.

Information needed to identify the device and its manufacturer, and any safety and performance information relevant to the user, or any other person, as appropriate, has to be available on the manufacturer's website.

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.

Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized symbols. Any symbol or identification colour used shall conform to the harmonized standards or CS. In areas for which no harmonized standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

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[3] Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices.

For whom (intended user)

A fundamental aspect is that the labeling shall be appropriate for the user. This means the medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the device, considering its intended purpose and the technical knowledge, experience, education or training of the intended user(s).

Specifically, the IFU shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

The content of the IFU may be aimed at healthcare professionals or at lay persons, individuals who do not have formal education in a relevant field of healthcare or medical discipline.

Since a device can be made available to the user or patient in various Member States, the labels and IFU shall be written in one of the official languages of the Union established by the relevant Member State, so to be readily understood. The language requirement may differ in each Member State depending on whether the device is intended for a professional or lay persons' use, as specified in each national legislation.

Specific products

Several standards have been published during the years to define the requirements for the information to be provided by the manufacturer of specific medical devices, including, for example, reprocessed devices, active and non-active implantable medical devices, ophthalmic optics.

Common specifications for the reprocessing of single-use devices[4] have been published and include requirements for the labeling and instructions for use.

It is not the purpose of this paper to list all the potential requirements for medical devices and IVDs. Manufacturers should be aware of standards and requirements for their devices.

[4] Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices.

Harmonized standards

Harmonized standards have a specific role in demonstrating conformity as per the European Medical Devices Regulation 2017/745 (MDR) and In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR).

Article 8 in each regulation indicates that harmonized standards are those referenced in the Official Journal of the European Union (OJEU). Devices in conformity with relevant harmonized standards are presumed to be in conformity with the requirements of the regulation covered by those standards.

There is an increasing lag between the development of ISO standards and their harmonisation (i.e., their publication in the OJEU). The European Commission has been warned that there are harmonized standards that are poor and unharmonized standards that, instead, represent the current 'state-of-the-art.' The most novel devices are always ahead of the standards. This means that all the stakeholders involved in the conformity assessment need to be aware of both harmonized and unharmonized standard.

Harmonized standards currently represent the tools Notified Bodies and manufacturers are supposed to use, but the European Directives and Regulations allow them to use unharmonized standards if additional safety or performance evidence can be gathered through them. This leads to difficult discussions between Notified Bodies and manufacturers when a manufacturer meets an outdated harmonized standard and not a most recent standard.

It is important to underline that, even though it is not possible to impose the use of any specific standard, for medical devices there are exceptions for which standards can be considered as mandatory. This is the case for symbols and identification colours that "shall conform to the harmonized standards or Common Specifications"[5]

GSPR 23.1(h) MDR / 20.1(h) IVDR

Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized symbols.

Any symbol or identification colour used shall conform to the harmonized standards or CS.

In areas for which no harmonized standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

when harmonized standards containing indications on symbols or colour coding are available.

The EN ISO 15223-1:2021 *Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements* (ISO 15223- 1:2021) is the harmonized standard that has been published in the OJEU to date for the MDR and the IVDR.

[5] AIMDD, Annex I, point 14; MDD, Annex I, point 13.2.; IVDD, Annex I, point 8.2.; MDR, Annex I, point 23.1 h); IVDR, Annex I, point 20.1 h).

Use of symbols

Manufacturers are expected to identify standards and guidance documents that apply to their devices and consider what symbols are applicable.

Symbols are used to convey meaning without the need for written text. GSPR 23.1(h) (MDR)/ GSPR 20.18h) (IVDR) states “where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized symbols”. EN ISO 15223-1:2021 is the harmonized standard that provides symbols. Manufacturers should be aware of product specific standards that provide information on symbols to be used. GSPR 23.1(h) requires that “in areas for which no harmonized standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.”

For devices that do not require an IFU, manufacturers should consider the risk of not providing an explanation for the symbols in their risk management documentation and implement appropriate control measures to mitigate the risk.

MDCG 2019-8 is a Medical Device Coordination Group document that provides a list of symbols recommended for use on the Implant Card relating to the application of Article 18.

Lack of recycling symbols

At the British Orthopaedic Association annual congress in 2023, it was reported that much of the packaging lacked recycling symbols, despite being made of recyclable materials. The lack of proper waste sorting and disposal not only contributes to environmental pollution but also increases operational costs associated with waste management. Manufacturers may need to consider incorporating recycling symbols on their packaging to address this problem.

Economic Operators responsibilities

Labeling requirements are not solely a manufacturer responsibility. Other economic operators likewise have related obligations.

Manufacturer

As detailed in Article 10 of the Regulations, the manufacturer is responsible for ensuring the device is accompanied by the information defined in GSPR 23 (MDR) /GSPR 20 (IVDR), including the implant card, when applicable, as well as that the information is written in the proper official Union language(s) and is comprehensible to the intended user.

The manufacturer shall also implement and maintain the post-market surveillance system, which may lead to updates to the labeling.

A further control is ensured by the manufacturer’s person responsible for regulatory compliance (Article 15), who shall be responsible for ensuring that the conformity of the devices is appropriately checked before a device is released, that the technical documentation (labeling included) is drawn up and kept up-to-date, and that the post-market surveillance obligations are complied with.

Authorised representative

The authorised representative (Article 11) is responsible to verify that the technical

documentation has been drawn up and, in case the manufacturer violates its obligations, shall terminate the mandate with the manufacturer.

It is worth underlining that the authorised representative is legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

A further layer is provided by the authorised representative's person responsible for regulatory compliance (Article 15), who is responsible for ensuring the tasks of the authorised representative as specified in the mandate referred to in Article 11(3) of the Regulations are fulfilled, tasks that include the verification of the technical documentation.

Importer

The importer obligations are covered by Article 13.

Before placing a device on the market, the importers shall verify that the device has been CE marked, that a manufacturer is identified and that an authorised representative in accordance with Article 11 has been designated by the manufacturer. Additionally, the importers shall verify that the device is labeled in accordance with the Regulations and accompanied by the required instructions for use and, where applicable, that a UDI has been assigned by the manufacturer in accordance with Article 27 (MDR)/Article 25 (IVDR).

In case of non-conformities, the importer shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. It shall also inform the competent authority of the Member State in which the importer is established in case the importer considers or has reason to believe that the device presents a serious risk or is a falsified device.

Importer details (i.e., name, registered trade name or registered trademark, registered place of business and the address at which they can be contacted) shall be indicated on the device or on its packaging or in a document accompanying the

device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

Distributor

The labeling is further checked by the distributor (Article 14).

Before making a device available on the market, the distributors shall verify that the device has been CE marked, that the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11) and, where applicable, that a UDI has been assigned by the manufacturer in accordance with Article 27 (MDR)/Article 25 (IVDR). A sampling method could be applied.

In case of imported devices, the distributor shall also confirm that the importer has complied with the requirements set out in Article 13(3).

In case of non-conformities, the distributor shall not make the device available on the market until it has been brought into conformity and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. The distributor shall also inform the competent authority of the Member State in which it is established in case it considers or has reason to believe that the device presents a serious risk or is a falsified device.

Activities covered by Article 16(2)

A natural or legal person (including distributors and importers) may:

- Provide or translate the information supplied by the manufacturer, in accordance with GSPR 23 (MDR)/GSPR 20 (IVDR), relating to a device already placed on the market and provide or translate further information which is necessary in order to market the device in the relevant Member State
- Change the outer packaging of a device already placed on the market (including a change of pack size), where the repackaging is necessary to market the device in the relevant Member State and if it is carried out without impacting the original condition of the device (therefore, excluding devices placed on the market in sterile condition).

This person shall indicate on the device or, if not practicable, on its packaging or in a document accompanying the device, the activity carried out together with its details (i.e., name, registered trade name or registered trademark, registered place of business and the address at which it can be contacted).

The Regulations, furthermore, provides that distributors and importers shall ensure that they have in place a quality management system to guarantee, among other things, that the translation of information is accurate and up to date, that the activities are performed maintaining the original condition of the device and that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question.

The Regulations also include provision for these distributors or importers to inform the manufacturer and the competent authority of the relevant Member State of the intention to make the relabelled or repackaged device available, providing a sample or mock-up of the relabelled or repackaged device if requested.

Label requirements

GSPR 23.2 (MDR)/GSRP 20.2 (IVDR) provides a list of requirements on information to be communicated through the labeling of the device. This section does not aim to present an exhaustive list of these requirements but more a highlight on significant changes introduced or clarified in the Regulations.

First and foremost, the use of symbols on the label, where appropriate, is a requirement from the Regulations as per GSPR 21.1 (h) (MDR)/ GSPR 20.1 (h) (IVDR):

"Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized symbols. Any symbol or identification colour used shall conform to the harmonized standards or CS. In areas for which no harmonized standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device".

This implies that, if there is an internationally recognized symbol for information that must be included on the label, it is mandatory to utilize that symbol. See the "use of symbols" section of this whitepaper.

The Regulations clarify or introduce the following requirements for the labeling:

- GSPR 23.2 (e) (f) of the MDR: the label must have an indication if the device contains or incorporates any of these substances:
  - 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
  - Restricted substances such as CMR, or endocrine-disrupting substances in the conditions set in GSPR 10.4.1.

  ISO 15223-1 §5.4 shall be considered for the selection of associated symbols.
- GSPR 23.2 (h) of the MDR/GSPR 20.2 (g) of the IVDR: the UDI carrier must appear on the label. For more information on UDI, refer to BSI whitepapers "**Understand the EU UDI system**" and "**European Union Medical Device Regulation and In Vitro Device Regulation: unique device identification.**"
- GSPR 23.2 (m) (MDR)/ GSPR 20.2 (l) (IVDR): 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.

  For implantable medical devices, the precautions related to the Magnetic Resonance imaging (MRI) environment must be considered. Guidelines for labeling may come directly from applicable standards (e.g., ASTM F2503 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment).
- GSPR 23.3 (a) (MDR)/ GSPR 20.3 (a) (IVDR): identifying which packaging layer is the sterile barrier.

  Four new oval shaped symbols have been introduced in the ISO 15223-1:2021 standard to identify the sterile barrier and any protective packaging layer that could be mistaken for the sterile barrier:
  - The sterile barrier(s) represented by solid line(s) and
  - Protective packaging represented by a dash line.

According to the description in ISO 15223-1:2021, the symbols shall be placed adjacent to or in combination with the sterility symbol listed in §5.2 of that same standard.

The Regulations do not actually specify which packaging layer needs to be labeled, only that the sterile barrier needs to be recognized as such.

The manufacturers must provide evidence that the sterile barrier packaging is adequately labeled and designed as part of the evidence for compliance with GSPR 11.1 (MDR and IVDR) and ISO 11607-1 §7 Usability evaluation for aseptic presentation.

The information provided on the label and in the IFU are connected:

- GSPR 23.1(a) (MDR)/ GSPR 20.1(a) (IVDR): some of the information required on the label shall also appear in the IFU: GSPR 23.2 (a), (c), (e), (f), (k), (l), (n) and (r) (MDR)/ GSPR 23.2 (a), (c), (k), (l) and (p) (IVDR).
- GSPR 23.1(h) (MDR)/ GSPR 20.1(h) (IVDR): the symbols may require to be described in the IFU.

Additional requirements for labeling may come directly from applicable standards (e.g., ASTM F2503 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment).

Nanomaterials

Whilst not being specifically called for in the MDR, the presence of nanomaterials as defined in Article 2 (18) of the MDR are to be considered for their identification in the label with the associated symbol from ISO 15223-1:2021.

BSI published a whitepaper on nanotechnology - " **Nanotechnology - What does the future look like for the medical devices industry?**" and a leaflet " **Nanomaterials and nanotechnology in medical devices**"

IFU requirements

GSPR 23.4 (MDR)/ GSPR 20.4 (IVDR) provides a list of requirements on information to be communicated through the lFU of the device. This section does not aim to present an exhaustive list of these requirements but more a highlight on significant changes introduced or clarified in the Regulations.

Electronic IFU (eIFU)

As per GSPR 23.1 (f) (MDR)/ GSPR 20.1 (f) (IVDR), 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 rule adopted pursuant to the MDR or, for IVDs, when the device is intended for professional use only, with the exception of devices intended for near-patient testing.

The state-of-the-art requirements for electronic IFU for medical devices is listed in Commission Implementing Regulation (EU) 2021/2226 (replacing EU No 207/2012).

As per (EU) 2021/2226, key considerations for all manufacturers of medical devices providing an eIFU include:

- Article 7(1): website used by the manufacturer to disseminate the eIFUs shall be operating and functional, providing ready access to the eIFUs.
- Articles 7(2(d)) and Article 9: website meets the requirements of Regulation 2016/679 for the protection of personal data collected there.
- Article 5 (11): website mentions in which Union languages the manufacturer provides the instructions for use in electronic form.
- Article 5(13), Article 7(2(f)) and Article 9: website shall include all previous electronic versions and date of publication.
- Article 7(2(b)) and Article 9: website (electronic data and content) shall be protected against unauthorised access and tampering of content in accordance with Article 4(1(e)).
- Article 7(2(e)): website shall continue to be directly accessible via a stable internet address during the following periods:
  - For implantable devices and devices without a defined expiry date: for 15 years after the last device has been placed on the market
  - For non-implantable devices with a defined expiry date: at least 2 years after the expiry date of the last produced device and for 10 years after the last device has been placed on the market.

As per (EU) 2021/2226, key considerations for manufacturers providing an eIFU instead of a paper IFU include:

- Article 3: confirm device allowed to provide electronic IFU instead of paper IFU

- Article 5(3): the manufacturer's procedures shall demonstrate they have a system in place to provide the instructions for use in printed paper form at no additional cost for the user within the time period set out in the risk assessment and at the latest within 7 calendar days of receiving a request from the user or at the time of delivery of the device, if so requested at the time of order.
- Article 5(8) - manufacturer's procedures shall demonstrate they have a system in place to clearly indicate when the instructions for use have been revised and to inform each user of the device thereof if the revision was necessary for safety reasons.
- Article 5(12): manufacturer shall have effective systems and procedures in place to ensure that device users who have downloaded instructions for use from the website can be informed in case of updates or IFU-related corrective actions.
- Article 7(2(a)): website contents shall be read with freely available software.
- Article 7(2(c)): website shall be designed to minimize server downtime and display errors.

Key considerations for manufacturers hosting an electronic copy of the IFU on the website to meet GSPR 23.1 (MDR): when is full or partial compliance with (EU) 2021/2226 required?

Full compliance:

- When all or selected sections of the IFU necessary to demonstrate compliance with the GSR23.4 requirements is only made available in electronic format: e.g., full IFU, or when not provided with the device: instruction for sterilisation, information on the combination with other devices/ accessories, surgical technique.
- When all or selected languages accepted in the Member States where the device is envisaged to be sold is only made available in electronic format.

Partial compliance:

- When paper IFU is available and an electronic copy of the paper IFU is hosted on the manufacturer's website. In this situation the manufacturer shall demonstrate that the up-to-date information is maintained on the website and confirm compliance to sections (b), (d), (e) and (f) of paragraph 2 of Article 7 of (EU) 2021/2226.

IFU listing multiple devices

This approach may be intended to simplify the instruction provided to the users in the cases when there is typically a high overlap in the content of the information. Examples for these IFU include:

- Multiple implantable components intended to be used as a system.
- Implants and associated accessories / instruments.
- Multiple instruments.

The Regulations do not specifically prevent a manufacturer from using this approach. However, when using a single IFU for multiple devices, the manufacturer is responsible for ensuring that only information approved by the Notified Body is released to the users. In other words, an IFU covering multiple devices should not be placed on the market before all listed devices have received CE marking, after the Notified Body conformity assessments.

MRI environment

As detailed in GSPR 23.4(s) (MDR)/ GSPR 20.4.1(n) (IVDR), the manufacturer shall address warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields. In the absence of harmonized standards, guidance can be found in ASTM F2503 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment).

CMR substances

Substances classified as carcinogenic, mutagenic, or toxic for reproduction and endocrine-disrupting substances.

As detailed in GSPR 23.4(s) (MDR)/ GSPR 20.4.1(n) (IVDR), the manufacturer shall address precautions related to materials incorporated into the device that contain or consist of substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR) or endocrine-disrupting (ED) substances.

The presence of these substances shall be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, listing these substances. Appropriate symbols shall be used to disclose such type of presence.

Link to the SS(C)P

As detailed in Article 32 and GSPR 23.4(d) of the MDR, for implantable and Class III devices, other than custom-made or investigational devices, the manufacturer shall provide links to the summary of safety and clinical performance (SSCP) in the IFU. As per Article 29 of the IVDR, for class C and D devices, other than devices for performance studies, links to the summary of safety and performance (SSP) shall be provided on the label or instructions for use.

The SS(C)P should be made available to the public via EUDAMED. Prior to full implementation of the EUDAMED database, this can be accomplished on the manufacturer's website. Upon implementation of the database, the link may be redirected to EUDAMED.

Disclosure of residual risk

In accordance with GSPR 23.4(g) (MDR), it is mandated that the IFU includes details concerning all residual risks and undesirable side-effects. This means that when a residual risk or undesirable side-effect is identified in the risk management documentation, in the clinical evaluation, state-of-the-art or post-market surveillance, it needs to be disclosed in the IFU.

Single Use

As detailed in GSPR 23.4(p) (MDR), if the device bears an indication that it is for single use, the manufacturer shall provide information on known characteristics and technical factors 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 no instructions for use are required, this information shall be made available to the user upon request.

For IVDs, as per GSPR 20.4.1(n) (v) and GSPR 20.2(p) (IVDR) 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,

Reuse

As detailed in GSPR 23.4 (n) of the MDR and in GSPR 20.4.1(n) (vi) of the IVDR, the manufacturer shall state in the IFU, 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 that is, for medical devices, 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).

As per GSPR 23.4(o) of the MDR, the manufacturer shall also specify 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.

Qualitative and quantitative information on materials and substances to which patients can be exposed

As per MDR Annex I, 23.4(u), in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed is to be disclosed in the instructions for use.

The maximum concentration/quantity or the range of concentration/quantity (quantitative information) of the material and substance is to be disclosed. When applicable and relevant, tolerances shall be disclosed or included in the concentration/quantity value provided. Each material and substance shall have a specific quantitative value or range.

Definitions

Qualitative: a listing of a medical device's materials and substances of construction.

Quantitative: the proportion and amount (mass) of each material in the medical device.

The quantitative and qualitative information for all materials and or substances that can be exposed to the patient at a level of 0.1%w/w or higher should be disclosed; this is in line with the requirement of MDR Annex I, 10.4.5.

If a substance or material is at a level lower than 0.1% w/w and is identified in the risk documentation as a residual risk (e.g., allergen), quantitative and qualitative information for this substance/material shall also be disclosed.

Vigilance

As detailed in GSPR 23.4(z) (MDR)/GSPR 20.4.1(af) (IVDR), the IFU shall include 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.

Implant card requirements

Article 18 of the MDR describes the requirements of the Implant Card (IC) and information to be supplied to the patient with an implanted device. Further details and supporting information can be found in MDCG 2018-8. Guidance on Implant Card “Device Types” can be found in MDCG 2021-11.

Contents

Language: Information provided in the IC shall be stated in the language(s) determined by the concerned Member State. The use of symbols is recommended. Currently, there is no symbol for “Device Type”. As such, this information must be provided in the required languages.

Usability: Information in the IC shall be written so it can be readily understood by a lay person. This could be accomplished through grade level reading analysis or usability testing by lay persons. Manufacturers must also ensure that the health professional is able to complete the IC correctly. This could be accomplished via ergonomic analysis or ergonomic usability testing.

Lifetime: The IC shall contain any information regarding the expected lifetime of the device as well as any necessary follow-up.

Size: To meet the intent of Article 18, the IC dimensions should be the same size as credit cards/ID cards, which are 85.6mm x 53.98mm with a radius of 2.88 - 3.48mm. Text in the IC must be at least 2mm high.

Device Composition: The IC shall include information to ensure safe use, including the overall qualitative and quantitative information on the materials and substances to which patients can be exposed.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Request a quote

Your partner in progress

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