Medical Device Labels under EU-MDR

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Art. 2 - definition

‘label’ means 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;

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Art. 7 - Claims

In the labelling, instructions for use, making available, putting into service and advertising of devices**, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance** by:

(a) ascribing functions and properties to the device which the device does not have;

(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;

(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

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Art. 10 – General Obligations of Manufacturers

Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an **official Union language(s)** determined by the Member State in which the device is made available to the user or patient.

The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

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Official Union Languages

Country	Language
Austria	German
Belgium	French and Dutch and German
Bulgaria	Bulgarian
Croatia	Croatian (and English)
Cyprus	Greek (and English)
Czech	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish and Swedish (or English)
France	French
Germany	German (and English if justified)
Greece	Greek
Hungary	Hungarian
Iceland	Icelandic
Ireland	English (or English and Irish)
Italy	Italian

Country	Language
Latvia	Latvian
Liechtenstein	German
Lithuania	Lithuanian
Luxembourg	French or German or Luxembourgish
Malta	English or Maltese
The Netherlands	Dutch
Norway	Norwegian
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovak
Slovenia	Slovene
Spain	Spanish
Sweden	Swedish
Switzerland	German and French and Italian, EPU
Turkey	Turkish

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Entry into force of Art. 27(4)

UDI carriers shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers

	Class I	Class IIa & IIb	Class III
UDI on device labels	26.May.2025	26.May.2023	26.May.2021
Reusable devices	26.May.2027	26.May.2025	26.May.2023

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GSPR 23 – Label and Instructions for Use

23.1 General requirements regarding the information supplied by the Manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

(a) The **medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s)**. In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

(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.

(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.

(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.

(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.

(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.

(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**.

(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.

GSPR 23 – Label and Instructions for Use

23.1 Information on the Label

The label shall bear all of the following particulars:

(a) the **name or trade name of the device;**

(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**;

(c) the **name, registered trade name or registered trade mark of the manufacture**r and the address of its registered place of business;

(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**:

- ❑ a **medicinal substance**, including a human blood or plasma derivative, or
- ❑ **tissues or cells, or their derivatives, of human origin**, or
- ❑ **issues 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.: (**CMR & endocrine disruptors)**

(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;

(h) the **UDI carrier** referred to in Article 27(4) and Part C of Annex VII;

(i) an unambiguous indication of **the time limit for using or implanting the device safely**, expressed at least in terms of year and month, where this is relevant;

(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;

(k) an indication of any **special storage and/or handling condition that ap**plies;

(l) **if the device is supplied sterile, an indication of its sterile state and the sterilisation method**;

(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;

(n) **if the device is intended for single use, an indicatio**n of that fact. A manufacturer's indication of single use shall be consistent across the Union;

(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;

(p) **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';

(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 constit**uents responsible for achieving the principal intended action;

(s) for **active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number**

Symbols to be used in Labelling for replacing text as per Standard under Development ISO/FDIS 15223-1(1/3)

Revised Symbols

Manufacturer

Patient number

Consult instructions for use or consult electronic instructions for use

Caution

Do not resterilize

Do not use if package is damaged and consult instructions for use

Authorized representative in the European Community / European Union

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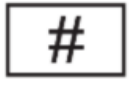
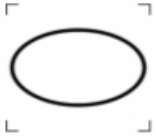
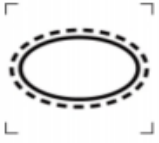
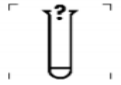
Symbols to be used in Labelling for replacing text as per Standard under Development ISO/FDIS 15223-1(2/3)

5.1.8. 	*Importer*
5.1.9. 	*Distributor*
5.1.10. 	Model number
5.1.11. 	Country of manufacture

5.2.11. 	Single *sterile* barrier system
5.2.12. 	Double *sterile* barrier system
5.2.13. 	Single *sterile* barrier system with protective packaging inside
5.2.14. 	Single *sterile* barrier system with protective packaging outside

5.4.6. 	Contains human blood or plasma derivatives
5.4.7. 	Contains a medicinal substance
5.4.8. 	Contains biological material of animal origin
5.4.9. 	Contains biological material of human origin
5.4.10. 	Contains hazardous substances

5.5.6. 	For IVD performance evaluation only
5.6. Transfusion/infusion	
5.6.1. 	Sampling site
5.6.2. 	Fluid path

5.4.11. 	Contains nano materials
5.4.12. 	*Single patient multiple use*

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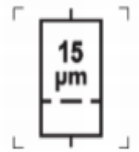
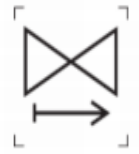
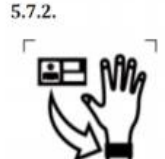
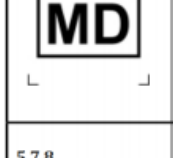
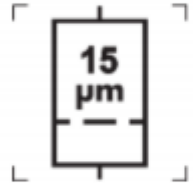
Symbols to be used in Labelling for replacing text as per Standard under Development ISO/FDIS 15223-1(3/3)

5.6.3. 	Non-pyrogenic
5.6.4. 	Drops per millilitre
5.6.5. 	Liquid filter with pore size
5.6.6. 	One-way valve

5.7.1. 	Patient number
5.7.2. 	Patient name
5.7.3. 	Patient identification
5.7.4. 	Patient information website

5.7.5. 	Health care centre or doctor
5.7.6. 	Date
5.7.7. 	*Medical device*
5.7.8.	Translation

5.7.9. 	Repackaging
5.7.10. 	Unique Device Identifier

5.6.4. 	Drops per millilitre
5.6.5. 	Liquid filter with pore size
5.6.6. 	One-way valve

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Example (1/2)

Information that should be included in an MDR-compliant label

Device name	Intramedullary Hip Nail called 'PRODUCT NAME'
Company Name	'COMPANY NAME'
Device Identification	Class IIb implantable device
CE mark	CE certified by TUV-SUD
Material	Stainless steel or titanium
Ref No.	XYZ123
Lot No	1234DDDDYYxzz
Expiry Date	31.Dec.2022
Warnings	❑ Do not re-use ❑ Do not resterilise ❑ Do not use if package is damaged ❑ Consult Instructions of Use before Use
Sterilization method	Steam sterilization
Storage method	4-27°C
Manufacturer	Name of Manufacturer
EC Representative	Name of EC Rep
UDI-DI	
Languages	EN - FR
Patient information website	www.EXAMPLEPRODUCT.com
Electronic Instructions of Use	

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Example (1/2)

Proposed format of an MDR-compliant label

Note:

- Structured proposed herein is not mandatory.
- Final format and contents of an MDR-compliant label depends on the medical device's nature
- Examples of other items to be included in a label:
  - Warning for CMRs
  - No of times a MD has been reprocessed
  - Indication the MD contains tissue or cells of animal or human origin
  - Overall composition for absorbed devices

COMPANY NAME

PRODUCT NAME

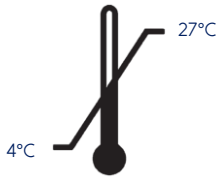
MD

EN: Hip Intramedullary Nail; 19.5cm short
FR: Clou Intramédullaire Femoral; 19.5cm court

En: Material: Titanium
Fr: Matière : Titane

Name of Manufacturer
Full Address of Manufacturer

EC REP Name & Full Address of EC Representative



REF XYZ123

LOT 1234AB


2022-12-31

Date of manufacture & Country Code

CE 0123


www.EXAMPLEPRODUCT.com

UDI

(01)123456789123(17)221231(10)1234AB(21)X1234

Importers-Distributors

Art. 13(3) – General Obligations of Importers

Importers **shall** indicate on the device or on its packaging or in a document accompanying the device **their name, registered trade name or r**egistered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

Art. 14(3) – General Obligations of Distributors

Distributors **shall** ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

There is no requirement to state the distributor in labels

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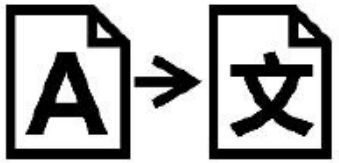
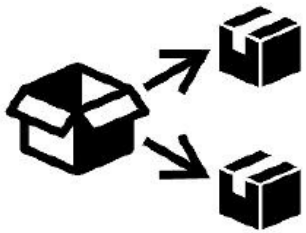
Relabeling & changes in packaging

Art. 16(3) – Cases in which obligations of manufacturers apply to importers, distributors or other persons

A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 2 **shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the dev**ice, the activity carried out together with its name, registered trade **name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.**





(a) **provision, including translation**, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;

(b) **changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State** and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market **in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackagi**ng

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