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Symbols to be used on labelling (ISO 15223)

&

Information to be provided by the manufacturer (ISO 20417)

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Symbols to be used on labelling (ISO 15223) & Information to be provided by the manufacturer (ISO 20417)

- ISO 15223 – changes
- ISO 15223 – new
- ISO 15223 current status
- ISO 20417 – new
- ISO 20417 overview of contents
- ISO 20417 current status

Orthopaedic

Dental

Active Implantable Devices

Active Devices

IVDs

Vascular

General Devices

Biological Substances

Drug-Device Combination

Symbols to be used on labelling (ISO 15223)

- Introduces some new symbols
- Updated text for other symbols

Safety Sign (ISO 7010)	Symbol (ISO 15223)
sign giving a general safety message, obtained by a combination of a colour and geometric shape and which, by the addition of a graphical symbol, gives a particular safety message	graphical representation appearing on the label and/or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

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Symbols to be used on labelling (ISO 15223)

- New symbols required by EU Regulations

- Updates to add clarity to existing symbols and definitions

- Draft status – final draft is in progress

Symbols to be used on labelling (ISO 15223)

EN ISO 15223-1:2016		ISO/DIS 15223-1	
3.1	**characteristic information** information that represents the property or properties of a symbol	No change	3.1
3.2	**description** normative text which defines the purpose, application and use of the symbol	No change	3.2
3.3	**label** written, printed or graphic information provided upon the medical device itself	**label** written, printed or graphic information marked on the item itself, or on the packaging of each item, or on the packaging of multiple items	3.3
3.4	~~**labelling**~~ ~~information supplied by the manufacturer that is provided for, associated with, or affixed to, a medical device or any of its containers or wrappers~~		

Symbols to be used on labelling (ISO 15223)

EN ISO 15223-1:2016		ISO/DIS 15223-1	
3.5	**symbol** ~~used in medical device labelling~~ graphical representation appearing on the label (3.3) and/or associated documentation of a medical device that communicates characteristic information (3.1) without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people	**symbol** graphical representation appearing on the label (3.3) and/or associated documentation of a medical device that communicates characteristic information (3.1) without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people	3.4
3.6	**title** unique name by which a graphical symbol is identified and spoken of	**title** unique name by which a graphical symbol is identified and referenced	3.5

Symbols to be used on labelling (ISO 15223)

5.1.1 [factory symbol] 23.2(c)	**Manufacturer** This symbol shall be accompanied by the name and address of the manufacturer ~~(i.e. the person placing the medical device on the market),~~ adjacent to the symbol. Update to notes; deleted 3 and 6, references to Directives replaced with Regulations
5.1.2 **EC** | **REP** 23.2(d)	**Authorized representative in the European Community / European Union** Update to notes; If multiple symbols (i.e., Authorized Representative, Importer, Distributor, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.
5.7.1 [person with # symbol] Article 18	**Patient number** Indicates a unique number associated with an individual patient. Added to Notes: NOTE 1 The hash mark (#) is part of the symbol. The patient number appears adjacent to the symbol. NOTE 2 Usage would be to indicate a data entry field or location (e.g. medical device input screen or implant card) or in information provided to the patient.

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Symbols to be used on labelling (ISO 15223)

Revised

5.2.6 23.2(l)	**Do not resterilize** Added restriction: This symbol is only to be used when there is an accompanying Sterile symbol (5.2.1 to 5.2.5 or 5.2.10). This symbol is not to be used on reusable medical devices that are intended to be sterilized between uses.
5.2.8 23.2(l), 23.3(j)	**Do not use if package is damaged and consult instructions for use** Updated description; Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the Instructions for Use for additional information.

Symbols to be used on labelling (ISO 15223)

5.4.3 23.2(m)	**Consult instructions for use or consult electronic instructions for use** Indicates the need for the user to consult the instructions for use When the instructions for use and patient information are located within the same electronic instructions for use, a manufacture may choose to use this symbol to indicate both. ~~When used to indicate an instruction to consult an electronic instructions for use (eIFU), this symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer's eIFU website or any other appropriate indication on the use of eIFU. The indicator may be placed either alongside, beneath or surrounding the symbol~~
5.4.4 23.2(m)	**Caution** To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. ~~Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.~~

Symbols to be used on labelling (ISO 15223)

5.1.8 Article 13.3	**Importer** Indicates the entity importing the medical device into the locale This symbol shall be accompanied by the name and address of the importing entity, adjacent to the symbol
5.1.9	**Distributor** Indicates the entity distributing the medical device into the locale This symbol shall be accompanied by the name and address of the importing entity, adjacent to the symbol
5.1.10 Article 18.1(a) Annex VI B.11	**Model number** To identify the model number or type number of a product This symbol shall be accompanied by the model number or catalogue number of the product, adjacent to the symbol.
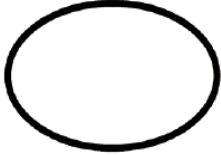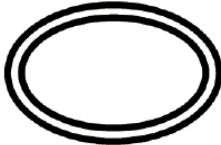
Symbols to be used on labelling (ISO 15223)

5.1.11 FACTORY SYMBOL CC	**Country of manufacture** To identify the country of manufacture of products In the application of this symbol, the "CC" shall be replaced by either the two letter country code or the three letter country code defined in ISO 3166-1.
5.2.10 STERILE | VH2O2 23.2(l), 23.3(c)	**Sterilized using vaporized hydrogen peroxide** Indicates a medical device that has been sterilized using vaporized hydrogen peroxide

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Symbols to be used on labelling (ISO 15223)

5.2.11	**Single sterile barrier system**
	Indicates a single sterile barrier system
	This symbol shall be placed adjacent to or in combination with symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10
	NOTE 1 A solid line identifies a sterile barrier system.
23.3(a)	NOTE 2 Additional information can found in ISO 11607-1 and ISO 11607-2.
5.2.12	**Double sterile barrier system**
	Indicates two sterile barrier systems
	This symbol shall be placed adjacent to or in combination with symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10
	NOTE 1 A solid line identifies a sterile barrier system.
23.3(a)	NOTE 2 Additional information can found in ISO 11607-1 and ISO 11607-2.

Symbols to be used on labelling (ISO 15223)

5.2.13 23.3(a)	**Single sterile barrier system with protective packaging inside** Indicates a single sterile barrier system with protective packaging inside This symbol shall be placed adjacent to or in combination with symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10 NOTE 1 The protective packaging located inside the sterile barrier system is designed to prevent damage to the contents or to help with aseptic presentation. It does not provide a microbial barrier to maintain sterility. NOTE 2 Additional information can found in ISO 11607-1 and ISO 11607-2.
5.2.14 23.3(a)	**Single sterile barrier system with protective packaging outside** Indicates a single sterile barrier system with protective packaging outside This symbol shall be placed adjacent to or in combination with symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10 NOTE 1 The protective packaging located outside the sterile barrier system is designed to prevent damage to the sterile barrier system and the contents. The protection can be against physical hazards, particulate contamination or other environmental hazards, but it does not include a microbial barrier. NOTE 2 Additional information can found in ISO 11607-1 and ISO 11607-2.

Symbols to be used on labelling (ISO 15223)

5.4.6 23.2(e)	**Contains human blood or plasma derivatives** Indicates a medical device that contains or incorporates human blood or plasma derivatives. The embedded cross may be deleted or replaced with another element appropriate with cultural requirements
5.4.7 23.2(e)	**Contains a medicinal substance** Indicates a medical device that contains or incorporates a medicinal substance The embedded cross may be deleted or replaced with another element appropriate with cultural requirements
5.4.8 23.2(e)	**Contains biological material of animal origin** Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin GSPR: as referred to in Regulation (EU) No 722/2012 Non-TSE susceptible species? bovine, ovine, caprine, deer, elk, mink, cats
5.4.9 23.2(e)	**Contains biological material of human origin** Indicates a medical device that contains biological tissue, cells, or their derivatives, of human origin

Symbols to be used on labelling (ISO 15223)

5.4.10 10.4.5	**Contains hazardous substances** Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties
5.4.11	**Contains nano materials** Indicates a medical device that contains nano materials
5.4.12 ISO 20417 3.26	**Single patient - multiple use** Indicates a medical device that may be used multiple times (multiple procedures) on a single patient

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Symbols to be used on labelling (ISO 15223)

New

5.7.2 Article 18	**Patient name** Indicates the name of the patient NOTE Usage would be to indicate a data entry field or location (e.g. medical device input screen or implant card) or in information provided to the patient.
5.7.3 Article 18	**Patient identification** Indicates the identification data of the patient NOTE Usage would be to indicate a data entry field or location (e.g. medical device input screen or implant card) or in information provided to the patient
5.7.4 Article 18	**Patient information website** Indicates a website where a patient may obtain additional information on the medical product This symbol shall be accompanied by the website information (url) adjacent to the symbol NOTE Usage would be to indicate a data entry field or location on an implant card or in information provided to the patient
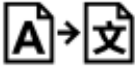
Symbols to be used on labelling (ISO 15223)

5.7.5	**Health care centre or doctor**
	To indicate the address of the health care centre or doctor where medical information about the patient may be found
	This symbol shall be accompanied, adjacent to the symbol, by the address of the health care centre or doctor
	NOTE 1 The embedded cross can be deleted or replaced with another element appropriate with cultural requirements.
Article 18	NOTE 2 Usage would be to indicate a data entry field or location (e.g. medical device input screen or implant card) or in information provided to the patient
5.7.6	**Date**
	To identify the date that information was entered or a medical procedure took place
	This symbol shall be accompanied, adjacent to the symbol, by the date appropriate for the use of the symbol
Article 18	NOTE Usage would be to indicate a data entry field or location (e.g. medical device input screen or implant card) or in information provided to the patient

Symbols to be used on labelling (ISO 15223)

5.7.7 **MD** 23.2(q)	**Medical device** Indicates the item is a medical device
5.7.8 Article 16.3	**Translation** To identify that the original medical device information has undergone a translation which supplements or replaces the original information This symbol shall be accompanied by the name and address of the entity that is responsible for the translation activity, adjacent to the symbol. NOTE 1 Translation activities cannot be allowed in all jurisdictions, however for some locales, translation activities are required to meet local language requirements. NOTE 2 If multiple symbols (i.e., Authorized Representative, Importer, Distributor, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated. This symbol should only be used when the translation activity was undertaken by someone other than the manufacturer.

Symbols to be used on labelling (ISO 15223)

5.7.9	**Repackaging**
	To identify that a modification to the original medical device packaging configuration has occurred
	This symbol shall be accompanied by the name and address of the entity that is responsible for the repackaging activity, adjacent to the symbol
	NOTE 1 Repackaging activities cannot be allowed in all jurisdictions, however for some locales, a change in the outer packaging, including changes to the pack size is needed or required.
	NOTE 2 Depending on the jurisdiction, additional information (i.e. date of repackaging) can be needed.
	NOTE 3 If multiple symbols (i.e., Authorized Representative, Importer, Distributor, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.
Article 16.3	This symbol should only be used when the repackaging activity was undertaken by someone other than the manufacturer.
5.7.10	**Unique Device Identifier**
	Indicates a carrier that contains Unique Device Identifier information
UDI	The use of this symbol is optional, but may be used when multiple data carriers are present on the label. If used, this symbol shall be placed adjacent to the Unique Device Identifier carrier.
23.2(h)	NOTE Used to identify which information is associated with Unique Device Identifier

Symbols to be used on labelling (ISO 15223)

No change				Update to notes, Restrictions, Additional requirements				
5.2.2 5.2.7	5.3.1 5.3.4 5.3.5 5.3.6 5.3.7	5.4.1 5.4.2 5.4.5	5.5.3 5.5.4 5.5.6	5.1.3 5.1.4 5.1.5 5.1.6 5.1.7	5.2.1 5.2.3 5.2.4 5.2.5 5.2.6 5.2.8 5.2.9	5.3.2 5.3.3 5.3.8 5.3.9	5.5.1 5.5.2 5.5.5	5.6.1 5.6.2 5.6.3 5.6.4 5.6.5 5.6.6

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Symbols to be used on labelling (ISO 15223)

A. Annex A – examples

B. Annex B – Use of general prohibition symbol and negation symbol - unchanged

C. Annex C – Terminology - Alphabetized index of defined terms

Symbols to be used on labelling (ISO 15223)

MDD/AIMD/IVDD

- ISO 15223:2020 would represent the state of the art for the Medical Device Directives.
- Conduct gap analysis and risk assessment.
- Should have a plan to implement the 2020 revision (once available) for BSI review.

MDR/IVDR

- ISO 15223:2020 would represent the state of the art for the Medical Device Directives and Regulation.
- It is anticipated the 2020 revision will be harmonized to the Regulations at the point of publication.
- Conduct risk assessment.

> 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 23.1(h) / 20.1(h)

Symbols to be used on labelling (ISO 15223)

Current Status

- Final **draft** international standard is being prepared
- Commenting ongoing for the harmonisation
- Publication remains anticipated in 2020

Summary

- ISO 15223:2020 expected in Q4 2020
- General updates to definitions & descriptions
- New symbols to meet regulatory requirements
- MDD gap analysis
- Define symbols for MDR

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Information to be supplied by the manufacturer (ISO 20417)

New standard replaces EN 1041:2008

General requirements for identification and labels on:

➢ medical device or accessory
➢ packaging
➢ marking of a medical device or accessory
➢ accompanying information

Does not specify the means by which the information is to be supplied

Terms and definitions aligned to:

➢ ISO 7010:2019
➢ ISO 13485:2016
➢ ISO 14971:2019
➢ ISO 15223-1:—
➢ ISO 16142-1:2016
➢ ISO 16142-2:2017
➢ IEC 62366-1:2015+AMD1:2019

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Information to be supplied by the manufacturer (ISO 20417)

ISO 20417:2020

- Main body of standard: 7 clauses, 35 pages
- 9 Annexes (informative): 37 pages

EN 1041:2008

- Main body of standard: 6 clauses, 5 pages
- 4 Annexes (informative): 14 pages

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Information to be supplied by the manufacturer (ISO 20417)

1 Scope

2 Normative references

3 Terms and definitions

4 General considerations

5 Information elements to be established

6 Requirements for accompanying information

7 Other information which is required to be supplied with the medical device or accessory

CONTENTS

Information to be supplied by the manufacturer (ISO 20417)

CONTENTS

Annex A (informative) Particular guidance and rationale

Annex B (informative) Example test method for assessing clearly legible

Annex C (informative) Example test method for assessing durability

Annex D (informative) Cross reference between the document and the requirements considered

Annex E (informative) Reference to the IMDRF essential principles and labelling guidances

Table E.1 — Correspondence between this document and the essential principles

Table E.2 — Correspondence between this document and the labelling principles

Annex F (informative) Reference to the essential principles

Table F.1 — Correspondence between the essential principles for non-IVD medical devices and this document

Table F.2 — Correspondence between the essential principles for IVD medical devices and this document

Annex G (informative) Reference to the general safety and performance requirements for medical devices

Annex H (informative) Reference to the general safety and performance requirements for IVD medical devices

Annex I (informative) Terminology — Alphabetized index of defined terms

Bibliography

Information to be supplied by the manufacturer (ISO 20417)

1 Scope

ISO 20417:2020

- Information supplied by the manufacturer for a medical device or accessory
- Includes MD, AIMD, IVD

EN 1041:2008

- Information supplied by the manufacturer for a medical device or accessory
- Includes MD, AIMD

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Information to be supplied by the manufacturer (ISO 20417)

2 Normative references

ISO 20417:2020

- Describes standards and other documents required for the application of ISO 20417

- Expanded / updated list vs 1041 (ISO 3166-1, ISO 639-1, ISO 1000, ISO 8601)

ISO 639-1:2002, Codes for the representation of names of languages – Part 1: Alpha-2 Code
ISO 639-2:1998, Codes for the representation of names of languages – Part 2: Alpha-3 code
ISO 639-3:2007, Codes for the representation of names of languages – Part 3: Alpha-3 code for comprehensive 164 coverage of languages
ISO 3166-1:2013, Codes for the representation of names of countries and their subdivisions – Part 1: Country codes
ISO 3864-1:2011, Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs 167 and safety markings
ISO 7000 (database), Graphical symbols for use on equipment – Registered symbols
ISO 7010:2019, Graphical symbols – Safety colours and safety signs – Registered safety signs
ISO 8601-1:2019, Date and time — Representations for information interchange — Part 1: Basic rules
ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971:2019, Medical devices – Application of risk management to medical devices
ISO 15223-1:—2, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ISO 16142-1:2016, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
ISO 16142-2:2017, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards
IEC 60417 (database), Graphical symbols for use on equipment
IEC 62366-1:2015+AMD1:2019, Medical devices – Part 1: Application of the usability engineering process to medical devices
ISO 80000-1:2009, Quantities and units – Part 1: General

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Information to be supplied by the manufacturer (ISO 20417)

3 Terms and definitions
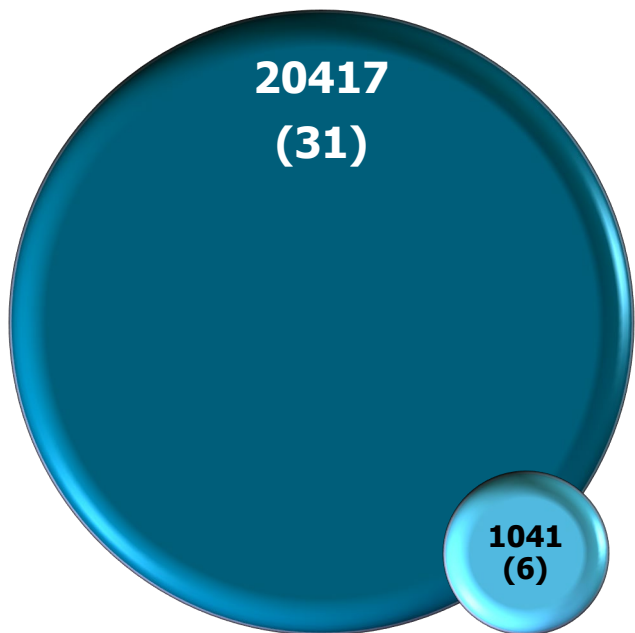
20417
(31)

1041
(6)

✓ Definitions aligned to expanded normative references

✓ Reflect the increase in detail of the new standard

Scope of ISO 20417
Information supplied by the manufacturer (3.10)

Label (3.12)

Packaging

Marking (3.16)

Accompanying information (3.2)
Auditory
Electronic
Multi-media
Printed
Tactile

Other information

Instructions for use (3.11)

Technical description (3.30)

Outside the Scope of ISO 20417
Example Documentation

Packing List

Customs Documentation

Marketing Information

Description — Optional

Commercial product name

Model number — Conditional⁹

Catalogue number

Distinct product identification — Required

1:1

Medical device: Identification

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Information to be supplied by the manufacturer (ISO 20417)

5 Information elements to be established

ISO 20417:2020		EN 1041
4	The risk management process of ISO 14971:2019 and the usability engineering process of IEC 62366-1:2015+AMD1:2019 should be used to determine the information, including information for safety, to be provided in the information supplied by the manufacturer	4.1
4	Language, special skills, use environment	-
4	Requirement to be understandable by the intended user	5.2.2

Information to be supplied by the manufacturer (ISO 20417)

5 Information elements to be established

ISO 20417:2020		EN 1041
5.1	Units of measurement ISO 80000-1:2009	4.2
5.2	Graphical information - Explain in accompanying information – unless not required - Symbols standards referenced	4.2
5.3	- Clearly identify the language. Refers to ISO 639 - Clearly identify country if multiple contact details. Refers to ISO 3166-1:2013	4.3
5.4	Unless specified by jurisdiction use date format as ISO 8601-1:2019	4.4
5.5	- Specifies address – street/road, number/house/floor, city, state/region, postal code, country - street/road and number/house/floor may be omitted if a postal code covers this - Prohibits PO Box	5.1.2

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Information to be supplied by the manufacturer (ISO 20417)

5 Information elements to be established

ISO 20417:2020		EN 1041
5.6	Commercial product name	-
5.7	Model number - medical device, an accessory or a medical device family that have shared characteristics - may be associated with multiple catalogue numbers	-
5.8	Catalogue number - assigned to medical device, or a combination of medical devices or accessories - unique catalogue number shall be related to a single, defined product specification - Multiple catalogue numbers may be associated with a single model number	-
5.9	Production controls – use at least one of: - lot number - serial number - for medical devices containing cell tissues, donor identification information - year and month by which it is to safe to use - year and month of manufacture	4.5.3

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Information to be supplied by the manufacturer (ISO 20417)

5 Information elements to be established

ISO 20417:2020		EN 1041
5.10	Unique device identifier - If required by the authority having jurisdiction This identifier shall have a 1:1 relation to: - a single catalogue number - a single model number - a single commercial product name	-
5.11	Types of use/reuse assigned at the level of model number or catalogue number - single use - single patient multiple use - multiple patient multiple use	-
5.12	Sterile – identify as sterile and with method Sterile/non-sterile versions should have different model or catalogue numbers	-

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	label

ISO 20417:2020		EN 1041
6.1	Requirements for information to be supplied on the label	-
6.1.1	Minimum requirements for the label Human readable Marked on device where possible Unless omission of these markings does not adversely affect the benefit/risk balance	-
6.1.2	Label of a medical device or accessory shall include - Name or trade name and the full address of the manufacturer and - Authorised representative - Country of manufacture may be used (refers to standards)	-

EC REP

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	label

ISO 20417:2020		EN 1041
6.1.3 a	Identify the device and its use on the label. Model/catalogue/name/description	-
6.1.3 b	- Any special storage conditions - Any special operating instructions for immediate attention of the user - Any warnings or precautions for immediate attention of the user May be kept to a minimum, in which case, more detailed information in the IFU	-
6.1.3 c	Contains known allergens as well as phthalates or other substances In a concentration that is above 0,1 % weight by weight That are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction	-

Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	label

ISO 20417:2020		EN 1041
6.1.3 d	Label must include (if applicable): eIFU Single use / do not re-use / single use only Single patient multiple use Limitations on re-use Sterile and method or symbol human blood or plasma derivatives biological material of human origin biological material of animal origin medicinal substances nanotechnology materials	-
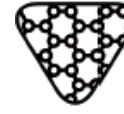
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STERILE R

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	label

ISO 20417:2020		EN 1041
6.1.4	Label must include (if applicable): Lot number Serial number Expiry date Date of manufacture (if no expiry date) UDI	-
6.1.5	Label must include (if applicable): Consult IFU	-
6.1.6	Safety sign (if needed) as per ISO 7010	-

LOT SN UDI

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	label

ISO 20417:2020		EN 1041
6.2	Identification requirements for detachable components of a medical device or accessory Use model, name, symbols etc	-
6.3	Legibility of the label - Legible when viewed from the intended position of user performing the related function - See Annex B	5.2.3
6.4	Durability of markings - Sufficiently durable to remain clearly legible over expected lifetime or shelf life - Clearly legible under reasonably foreseeable environmental and mechanical impacts of use - Removable only with an object that can be used to secure or release a fastener or by force - See Annex C	5.2.4

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	Pack

ISO 20417:2020	EN 1041
6.5.1 Information to be provided on the packaging: name or trade name and address authorized representative unique device identifier Lot number Serial number For medical devices containing cell tissues, donor identification information Expiry date Manufacture date Distinctive identification (model, catalogue number) Single patient / multiple use	-

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information

Pack

ISO 20417:2020	EN 1041
6.5.2 Packaging for the lay user: In addition to the requirements of 6.5.1, if the medical device or accessory is intended to be presented to the lay user for retail sales and is intended for use by a lay user, the sales packaging shall allow the identification of the information needed by the lay user including, as a minimum all of the following: - statement of intended use, unless the purpose is obvious to the intended lay user - the information needed to select the proper size, if applicable - any special requirements for a battery-powered - any necessary contraindications, warnings or precautions for immediate attention of the user - safe disposal information - visible under expected conditions of sale	-

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	Pack

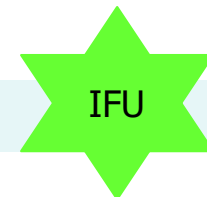| ISO 20417:2020	EN 1041
6.5.3 Special conditions indicated on the packaging: - Special handling measures to be taken during transport or storage - Premature unpackaging safety signs - Sterile / method - Expiry date - Indication permitting the sterile packaging to be recognized as such - What to do if the sterile packaging is damaged or unintentionally opened before use	-

Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6	Requirements for information in the instructions for use and technical description	-
6.6.1	information accompanying the medical device or accessory shall include: - the information specified for inclusion in the instructions for use - the information specified for inclusion in the technical description - the justification for any omission shall be evaluated according to ISO 14971:2019. the information specified for inclusion in the technical description may be included in the IFU	-

portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing*, transport or storage for the *expected lifetime* of a *medical device*

Note 1 to entry: The *technical description* may be included in the *instructions for use*

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6	Requirements for information in the instructions for use and technical description	-
6.6.1	name or trade name and full address of manufacturer and authorised representative - Contact information of the manufacturer - Device identity (commercial product name / device family name / model / catalogue number) - Device description	-
6.6.1	may include separate accompanying information for the professional user and the lay user - Consistent - State the version - Readily understandable - Supplemented by drawings / diagrams	-

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020	EN 1041
6.6.2 The instructions for use shall document all the following - the general information of 6.6.1 - the use of the medical device or accessory as intended by the manufacturer - information for safety necessary to safely use the device in accordance with specifications - the 'statement of intended use' - claimed performance - explanation of any residual risk, including any foreseeable adverse events or side effects - for the user or conveyed by user to patient	-
6.6.2 Residual risk conveyed as: - limitations - contraindications - precautions - warnings	-

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6.2	Unique identifier for IFU	-
6.6.2	Parts of the medical device that cannot be safely serviced or maintained while in use with patient	-
6.6.2	Safe disposal consider infection / microbial / environmental / physical hazards	-
6.6.2	Preparatory treatment or handling of the device before ready for use	-
6.6.2	The information contained in 6.1.2, 6.1.3 and 6.5.3	-

> The *instructions for use* should contain only the information most likely to be useful to the *user* or *responsible organization*

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6.2	Include specifications the user requires to use the medical device appropriately	-
6.6.2	Information to determine whether the device is ready to perform safely and as intended - Final assembly / calibration - Acceptance or performance testing - Acceptance criteria	-
6.6.2	Nature, and frequency, of preventative and regular maintenance	-
6.6.2	Identification of any consumable components and how to replace them	-
6.6.2	Calibration and control of risk associated with installation, calibration, servicing	-

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6.2	Quality control procedures to verify that the device performs as intended - Procedure - Instructions on frequency of use - Limitations of procedure - How the user should interpret procedure results, including description of acceptance - Actions to take for test failure	-
6.6.2	Requirements for - Sterile field - Training - User qualifications	-

Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6.2	If device supplied sterile, include instructions to be followed in the event of the sterile packaging being damaged or unintentionally opened before use	-
6.6.2	If device supplied non-sterile with the intention that it is sterilized before use, include the appropriate processing instructions for sterilization	-
6.6.2	Reusable devices: - processing information - when it can no longer be used or maximum reuses	-

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6.2	Include information of any warnings, precautions, measures to be taken and limitations of use	-
6.6.2	User and patient to report any serious incident	-
6.6.2	Where multiple devices are provided to single user / location, may provide single copy of IFU	-
6.6.2	Identify medicinal or biological substance - quantity, proportion, strength if in direct contact	-
6.6.2	Applicable instructions if packaging damaged, unintentionally opened, excursions in storage	-
6.6.2	Text on electronic displays intended for the user, shall be clearly legible	-
6.6.2	Limitations or incompatibilities in the choice of substances to be delivered	-

Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6.2	- Nature / type / intensity / distribution / recommended dose of the emitted radiation - Ways of avoiding misuse and of appropriately reducing the risks - Means of protecting the patient, the user, or a third party from unintended radiation	-
6.6.3	Additional requirements for the instructions for use for a lay user	-
6.6.3	Identify the patient is an intended user or that the medical device is intended for self-testing	-
6.6.3	Circumstances when the user should consult with a healthcare professional	-
6.6.3	Warning against servicing and maintenance while in use	-
6.6.3	Functions safe / not safe to use / maintenance	-

Information to be supplied by the manufacturer (ISO 20417)

IFU

6 Requirements for accompanying information	

ISO 20417:2020		**EN 1041**
6.6.3	Format appropriate for lay user	-
6.6.3	Enable lay user to understand results / confirm it is operating as intended	-
6.6.3	Identify the patient is an intended user or that the medical device is intended for self-testing	-
6.6.4	Requirements for technical description	-
6.6.4	If separate from IFU include 6.6.1 and 6.6.2 a	-
6.6.4	If separate from IFU include testing / maintenance / characteristics / accuracy / precision	-
6.6.4	If separate from IFU include unique reference	-

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Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6.4	Data that is essential for safe use, transport and storage, maintenance or repair, and measures or conditions necessary for installing the medical device and preparing it for use	-
6.6.4	Purpose of the electronic interface / software / intended user of interface	-
6.6.4	Communication format, interface specifications, data attributes being exchanged	-
6.6.4	Summary of the testing performed on the interface to verify interoperability	-
6.6.4	Description of any fault tolerance behaviour, boundary condition testing, or fail safe	-
6.6.4	Known limitations (what the user should not do), contraindications, precautions and warnings	-
6.6.4	Recommended connections	-

Information to be supplied by the manufacturer (ISO 20417)

6 Requirements for accompanying information	IFU

ISO 20417:2020		EN 1041
6.6.5	If the manufacturer has a website, the IFU should be available on that website	-
6.6.5	May use two-dimensional code (e.g., QR Code) as specified in ISO 22742:2010	-
6.6.5	Access instructions and how to get paper copy	-

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Information to be supplied by the manufacturer (ISO 20417)

7 Other information which is required to be supplied with the medical device	Other

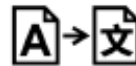| **ISO 20417:2020**		EN 1041
7.1	Importer name or trade name and full address	-
7.2	Distributor name or trade name and full address	-
7.3	Re-packager name or trade name and full address	-
7.4	Translator name or trade name and full address	
7.5	Regulatory identification	

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Information to be supplied by the manufacturer (ISO 20417)

Annex A (informative) Particular guidance and rationale

Annex B (informative) Example test method for assessing clearly legible

Annex C (informative) Example test method for assessing durability

Annex D (informative) Cross reference between the document and the requirements considered

Annex E (informative) Reference to the IMDRF essential principles and labelling guidances

Table E.1 — Correspondence between this document and the essential principles

Table E.2 — Correspondence between this document and the labelling principles

Annex F (informative) Reference to the essential principles

Table F.1 — Correspondence between the essential principles for non-IVD medical devices and this document

Table F.2 — Correspondence between the essential principles for IVD medical devices and this document

Annex G (informative) Reference to the general safety and performance requirements for medical devices

Annex H (informative) Reference to the general safety and performance requirements for IVD medical devices

Annex I (informative) Terminology — Alphabetized index of defined terms

Bibliography

CONTENTS

Information to be supplied by the manufacturer (ISO 20417)

Current Status

- Final **draft** international standard published
- Publication remains anticipated in 2020

Summary

- ISO 20417:2020 expected in Q2 2020
- Significant updates to standard vs 1041
- A lot of detail and normative references
- Overlap between EU requirements already – formalises into standard
- MDD gap analysis

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