INTERNATIONAL STANDARD

ISO 15223-1

Fourth edition
2021-07

Medical devices — Symbols to be used with information to be supplied by the manufacturer —

Part 1: General requirements

Dispositifs médicaux — Symboles à utiliser avec les informations à fournir par le fabricant —
Partie 1: Exigences générales

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 15223-1:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

— addition of 20 *symbols* that were validated as per ISO 15223-2;

— addition of 5 *symbols* previously published in ISO 7000, ISO 7001 and IEC 60417;

— deletion of the defined term "labelling";

— inclusion of defined terms from ISO 20417, ISO 13485 and ISO 14971;

— expansion of the examples given in Annex A;

— information about European regulations has been moved to informative notes throughout.

A list of all parts in the ISO 15223 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Medical device *manufacturers* and others in the supply chain must provide specific information on the *medical device* itself, as part of the packaging, or in the *accompanying information*. For simplicity and to avoid translation of text, this information can be provided as *symbols* that have a specific meaning. This document does not specify the information that needs to be provided, but does specify internationally recognized *symbols* for the provision of this specific information.

The *symbols* included in this document have been published in ISO 7000, ISO 7001, IEC 60417 or have been subjected to a formal *symbol* validation process.

This document is intended to be used by *manufacturers* of *medical devices* who market products in countries where there are specific language requirements. These *symbols* allow for a consistent portrayal of information. It can also be used by consumers or end users of *medical devices* who draw their supplies from a number of sources and can have varied language capabilities.

In this document, the conjunctive "or" is used as an "inclusive or"; so a statement is true if any combination of the conditions is true.

Terms defined in Clause 3 are shown in *italic type* throughout the document.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability;

— "must" indicates an external constraint that is not a requirement of the document.

Information marked as "NOTE" is intended to assist the understanding or use of the document. "Notes to entry" used in Clause 3 provide additional information that supplements the terminological data and can contain provisions relating to the use of a term.

Symbols added during the revision of this document were placed at the end of the pertinent section of Table 1 to preserve the numbering of existing *symbols* and facilitate easy referencing of existing *symbols* in other documents.

NOTE Numbers given in square brackets throughout the document refer to the Bibliography.

Medical devices — Symbols to be used with information to be supplied by the manufacturer —

Part 1: General requirements

1 Scope

This document specifies *symbols* used to express information supplied for a *medical device*. This document is applicable to *symbols* used in a broad spectrum of *medical devices*, that are available globally and need to meet different regulatory requirements.

These *symbols* can be used on the *medical device* itself, on its packaging or in the *accompanying information*. The requirements of this document are not intended to apply to *symbols* specified in other standards.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country code*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
accompanying information
information accompanying or *marked* on a *medical device* or accessory for the user or those accountable for the installation, use, processing, maintenance, decommissioning and disposal of the *medical device* or accessory, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the *medical device* or accessory.

Note 2 to entry: The *accompanying information* can consist of the *label*, *marking*, *instructions for use*, technical description, installation manual, quick reference guide, etc.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g. CD/DVD-ROM, USB stick, website).

Note 4 to entry: See Figure 1.

Note 5 to entry: The *label* can include the information on the packaging of the medical device.

Note 6 to entry: e-documentation can include any or all types of information supplied by the manufacturer partially or entirely.

Note 7 to entry: Marketing information is also known as promotional material.

Note 8 to entry: There is guidance or rationale related to accompanying information in ISO 20417:2021,[15] Annex A.

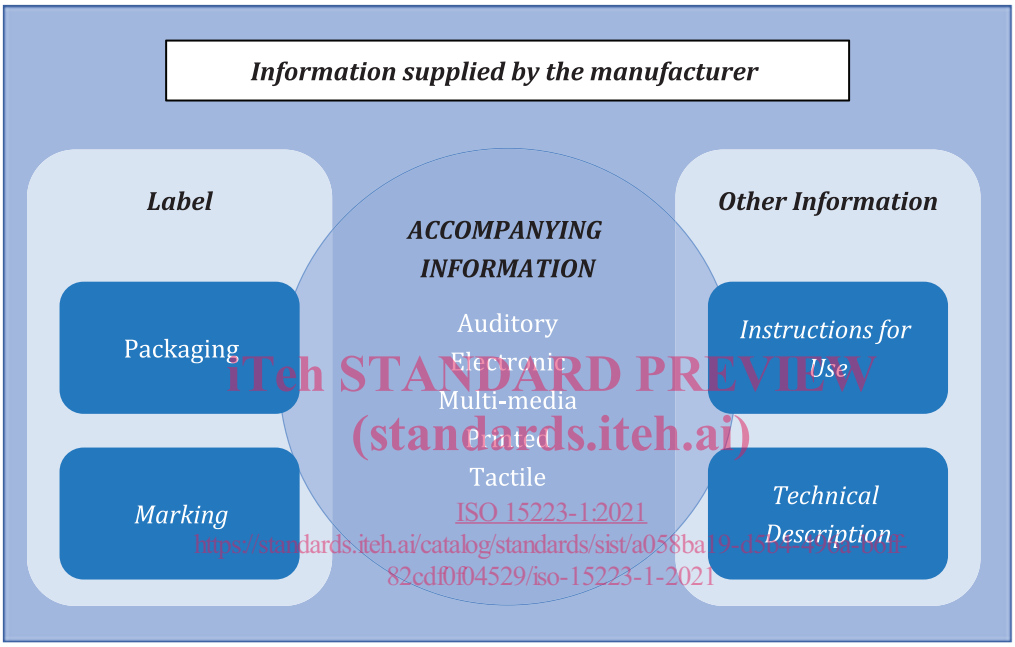

Figure 1 — Relationship of terms used to describe *information supplied by the manufacturer*

[SOURCE: ISO 20417:2021,[15] 3.2, modified — The following text has been removed from the graphic: "Scope of ISO 20417", defined term reference numbers and a side box containing information outside the scope of ISO 20417. Note 8 to entry has been added.]

3.2
catalogue number
commercial product name
commercial product code
value given by the *manufacturer* to identify a specific *medical device* or accessory as it relates to its form/fit, function and process (i.e. manufacturing processes requiring differentiation for the end user)

Note 1 to entry: A *catalogue number* shall consist of letters or numbers or a combination of these.

Note 2 to entry: For the purposes of this document, *commercial product code* should not be confused with the US FDA, "product code" or procode classification.

Note 3 to entry: Synonyms for *catalogue number* are "reference number" or "reorder number".

Note 4 to entry: See ISO 20417:2021, Figure 2.

[SOURCE: ISO 20417:2021,[15] 3.3, modified — The cross-reference in Note 4 to entry has been revised to be external to this document.]

3.3
description
normative text which defines the purpose, the application and the use of the *symbol* (3.19)

[SOURCE: IEC 80416-1:2008,[19] 3.2, modified — "and optional product area" has been removed.]

3.4
distributor
natural or legal person, different from the *manufacturer* or *importer*, in the supply chain who, on their own behalf, furthers the availability of a *medical device* or accessory to the user

Note 1 to entry: More than one *distributor* may be involved in the supply chain.

Note 2 to entry: For the purposes of this document, persons in the supply chain involved in activities such as storage and transport on behalf of the *manufacturer*, *importer* or *distributor*, are not *distributors*.

Note 3 to entry: Distribution activities alone do not include repackaging or otherwise changing the container, wrapper, or *accompanying information* of the *medical device* or *medical device* package other than providing the identification of the *distributor*.

[SOURCE: ISO 20417:2021,[15] 3.5]

3.5
importer
natural or legal person who imports a *medical device* or accessory into a locale that was manufactured in another locale for the purposes of marketing

[SOURCE: ISO 20417:2021,[15] 3.8]

3.6
information supplied by the manufacturer
information related to the identification and use of a *medical device* or accessory, in whatever form provided, intended to ensure the safe and effective use of the *medical device* or accessory

Note 1 to entry: For the purposes of this document, e-documentation is included in *information supplied by the manufacturer*.

Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from *information supplied by the manufacturer*. However, some *authorities having jurisdiction* (defined in ISO 16142-1:2016,[9] 3.1) can consider such supplemental information as *information supplied by the manufacturer*.

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the *medical device* and its *manufacturer*, and provide essential information about its safety, performance, and appropriate use to the user or other relevant persons.

Note 4 to entry: See Figure 1.

Note 5 to entry: There is guidance or rationale related to information supplied by the manufacturer in Annex A.

[SOURCE: ISO 20417:2021,[15] 3.10, modified — The cross-reference in Note 2 to entry has been added. Note 5 to entry has been added.]

3.7
instructions for use
IFU
package insert
portion of the *accompanying information* that is essential for the safe and effective use of a *medical device* or accessory directed to the user of the *medical device*

Note 1 to entry: For the purposes of this document, a user can be either a lay user or professional user with relevant specialized training.

Note 2 to entry: For the purposes of this document, instructions for the professional processing between uses of a *medical device* or accessory can be included in the *instructions for use*.

Note 3 to entry: *The instructions for use*, or portions thereof, can be located on the display of a *medical device* or accessory.

Note 4 to entry: *Medical devices* or accessories that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some authorities with jurisdiction.

Note 5 to entry: See Figure 1.

[SOURCE: ISO 20417:2021,[15] 3.11]

3.8
label
<*medical device,* accessory> written, printed or graphic information appearing on the item itself, on the packaging of each item, or on the packaging of multiple items

Note 1 to entry: For the purposes of this document, the term *labelled* is used to designate the corresponding act.

Note 2 to entry: *Label* includes the *marking* on the *medical device* or accessory.

Note 3 to entry: For the purposes of this document, information indicated on a graphical user interface (GUI) is considered as appearing on the item.

Note 4 to entry: See Figure 1.

[SOURCE: ISO 20417:2021,[15] 3.12]

3.9
lot number
batch code
batch number
lot code

production control containing a combination of letters or numbers associated with a single lot or batch

Note 1 to entry: The title of *symbol* 5.1.5 uses the synonym *batch code.*

[SOURCE: ISO 20417:2021,[15] 3.15, modified — Note 1 to entry has been added.]

3.10
manufacturer
natural or legal person with responsibility for the design or manufacture, or both, of a *medical device* with the intention of making the *medical device* available for use, under his or her name; whether or not such a *medical device* is designed or manufactured, or both, by that person themselves or on their behalf by another person(s)

Note 1 to entry: The natural or legal person has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the *medical devices* in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The *manufacturer's* responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design or manufacture, or both", may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a *medical device*; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a *medical device* that has already been supplied by another person for an individual patient, in accordance with the *instructions for use*, is not the *manufacturer*, provided the assembly or adaptation does not change the intended use of the *medical device*.

Note 5 to entry: Any person who changes the intended use of, or modifies, a *medical device* without acting on behalf of the original *manufacturer* and who makes it available for use under his own name, should be considered the *manufacturer* of the modified *medical device*.

Note 6 to entry: An authorized representative, *distributor* or *importer* who only adds its own address and contact details to the *medical device* or the packaging, without covering or changing the existing labelling, is not considered a *manufacturer*.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a *medical device*, the person responsible for the design, manufacture, or both, of that accessory is considered to be a *manufacturer*.

[SOURCE: ISO 14971:2019,[8] 3.9]

3.11
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *medical device* or accessory

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from "direct *marking*" as commonly described in unique device identification (UDI) standards and regulations. A UDI "direct *marking*" is a type of *marking*.

Note 3 to entry: See Figure 1.

[SOURCE: ISO 20417:2021,[15] 3.16]

3.12
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of *medical devices*;

— providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be *medical devices* in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal or human tissues, or both;

— devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016,[7] 3.11]

3.13
model number
model
letters, numbers or a combination of these assigned by a *manufacturer* to distinguish by function or type, a particular *medical device, accessory* or *medical device family* from another

Note 1 to entry: See ISO 20417:2021, Figure 2.

[SOURCE: ISO 20417:2021,[15] 3.17, modified — The cross-reference in Note 1 to entry has been revised to be external to this document.]

3.14
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2019,[8] 3.18]

3.15
serial number
production control containing a combination of letters or numbers, selected by the *manufacturer*, intended for quality control and identification purposes to uniquely distinguish an individual *medical device* from other *medical devices* with the same *catalogue number* or *model number*

[SOURCE: ISO 20417:2021,[15] 3.22]

3.16
single patient multiple use
<*medical device*, accessory> intended by the *manufacturer* to be reused on an individual patient for multiple uses

Note 1 to entry: A single patient multiple use *medical device* or accessory may require processing between uses.

Note 2 to entry: For an implantable medical device, the duration of a single use is from implanting to explanting the *medical device*.

[SOURCE: ISO 20417:2021,[15] 3.25]

3.17
single use
do not re-use
use only once
<*medical device*, accessory> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

Note 1 to entry: A single use *medical device* or accessory is not intended by its *manufacturer* to be further processed and used again.

[SOURCE: ISO 20417:2021,[15] 3.26]

3.18
sterile
free from viable microorganisms

[SOURCE: ISO 20417:2021,[15] 3.28]

3.19
symbol
graphical representation appearing on the *label* or associated documentation, or both, 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

Note 1 to entry: The *symbol* can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters (with sufficient justification).

[SOURCE: ISO 20417:2021,[15] 3.29]

4 General requirements

4.1 Future *symbols*

a) Future *symbols* proposed for inclusion in this document shall be validated in accordance with ISO 15223-2. *Symbols* registered under ISO 7000, ISO 7010, or IEC 60417 are exempt.

b) Any *symbol* proposed for inclusion in this document shall be applicable to a range of *medical devices* and have global or regional applicability.

4.2 Requirements for usage

a) When a need to use *symbols* as an appropriate method for conveying information essential for the proper use of a *medical device* is identified, the *symbols* given in Table 1 may be marked on the *medical device*, appear on its packaging or in *information supplied by the manufacturer*.

NOTE ISO and IEC maintain an online database of graphical *symbols* for use on equipment, which contains the complete set of graphical *symbols* included in ISO 7000, ISO 7001 and IEC 60417 available at https://www.iso.org/obp/ui/#home. This database shows each graphical *symbol* and identifies it by a reference number and a *title*. The graphical *symbols* are available in different formats (e.g. AI, DWG, EPS) and some additional data, as applicable, is provided.

b) The *manufacturer* shall determine the appropriate size for the *symbol* to be legible for its intended function.

NOTE 1 This document does not specify colours or minimum size for the *symbols* in Table 1, nor does it specify the relative size of *symbols* and that of indicated information.

NOTE 2 Guidance on the application of graphical *symbols* is found in IEC 80416-3:2002+A1:2011[20].

NOTE 3 Guidance on the use of the general prohibition *symbol* and the negation *symbol* is found in Annex B.

c) All dates and times presented in association with *symbols* shall use the conventions set out in ISO 8601-1 and ISO 8601-2.

4.3 Other *symbols*

Other standards specify additional *symbols* that are applicable to particular kinds or groups of *medical devices* or to particular situations. The bibliography provides examples of sources for additional *symbols*.

5 *Symbols*

a) When appropriate, information essential for proper use shall be indicated on the *medical device*, its packaging, or in the *accompanying information* by using the corresponding *symbols* given in Table 1.

b) A *manufacturer* may use any appropriate *symbol*.