DRAFT INTERNATIONAL STANDARD

ISO/DIS 15223-1

ISO/TC **210**

Secretariat: **ANSI**

Voting begins on:
2020-02-20

Voting terminates on:
2020-05-14

Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —

Part 1:
General requirements

Dispositifs médicaux — Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux —

Partie 1: Exigences générales

ICS: 01.080.20; 11.040.01

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 15223-1:2020(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

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

- Addition of 20 new *symbols* that were validated per ISO 15223-2
- Addition of 5 *symbols* from 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 informative annex containing examples
- Moved information about European Regulations to informative notes

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

Introduction

Medical device manufacturers and others in the supply chain must provide specific information that is essential for the safe and proper use of the *medical device*. This information can be on the *medical device* itself, as part of the packaging, or in other *accompanying information*. For simplicity and translation reasons, 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 7010, IEC 60417 or have been subjected to a formal *symbol* validation process.

This document is intended to be used by *manufacturers* of *medical devices* and others who desire to use these symbols to portray information without translation of text into multiple languages 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.

The verbal forms used in this document conform to usage described in ISO/IEC Directives, 129 Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that conformance with a requirement or a test is mandatory for conformance with this document;
- "should" means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;
- "may" is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);
- "can" is used to describe a possibility or capability; and
- "must" is used to express an external constraint.

Symbols added during the revision of this document were placed at the end of the pertinent section so as to preserve the numbering of existing *symbols* which facilitates easy referencing in other documents.

Medical Devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

1 Scope

This document identifies requirements for *symbols* used in *medical device* labelling that convey information on the safe and effective use of *medical devices*. It also lists *symbols* that satisfy the requirements of this document.

This document is applicable to *symbols* used in a broad spectrum of *medical devices*, which are marketed globally and therefore need to meet different regulatory requirements.

These *symbols* are *marked* on the *medical device* itself, placed on its packaging or placed in the associated *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 7000 (database), *Graphical symbols for use on equipment — Registered symbols*

ISO 7001:2019, *Graphical symbols — Public information symbols*

ISO 8601-1:2019, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2:2019, *Date and time — Representations for information interchange — Part 2: Extensions*

ISO 14971:2019, *Medical devices -- Application of risk management to medical devices*

ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes*

ISO 15223-2:2010, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

ISO 20417:----[1], *Medical Devices - Information to be supplied by the manufacturer*

IEC 60417 (database), *Graphical symbols for use on equipment*

IEC 80416-1:2008, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols for registration*

3 Terms and definitions

For the purposes of this document the following apply.

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

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

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

[1] Under preparation. Currently in FDIS stage.

— Numbers in square brackets refer to the Bibliography

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

[SOURCE: ISO 20417:---- [15], definition 3.2]

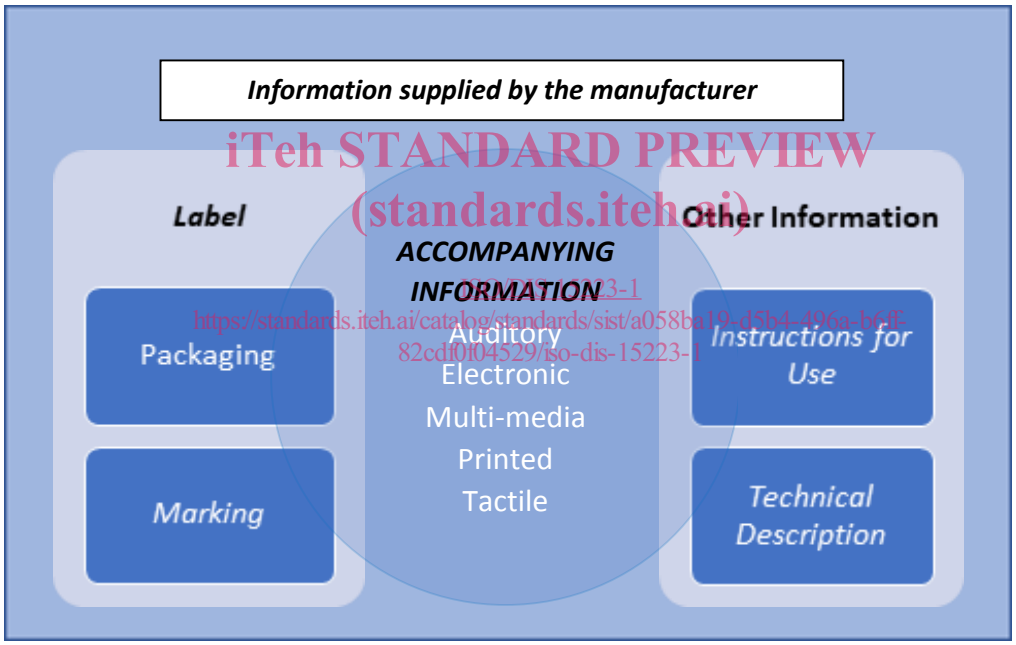

Figure 1 – Relationship of terms used to describe *information supplied by the manufacturer*

3.2
batch code
batch number
lot code
lot number
production control containing a combination of letters or numbers associated with a single batch or lot

[SOURCE: ISO 20417:---- [15], definition 3.15]

3.3
catalogue number
commercial product code
commercial product name
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.

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

Note 3 to entry: See ISO 20417:2020 Figure 2.

[SOURCE: ISO 20417:---- [15], definition 3.3 - modified to make note 3 an external reference]

3.4
characteristic information
information that represents the property or properties of a *symbol*

3.5
description
normative text which defines the purpose, application and use of the *symbol*

[SOURCE: IEC 80416-1:2008 [10], definition 3.2]

3.6
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*.

[SOURCE: ISO 20417:---- [15], definition 3.5]

3.7
importer
natural or legal person who imports a *medical device* or accessory into a locale, which was manufactured in another locale, for the purposes of marketing

[SOURCE: ISO 20417:---- [15], definition 3.8]

3.8
information supplied by the manufacturer
all 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* 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.

[SOURCE: ISO 20417:---- [15], definition 3.10]

3.9
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*.

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:---- [15], definition 3.11]

3.10
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

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: See Figure 1.

[SOURCE: ISO 20417:---- [15], definition 3.12]

3.11
manufacturer
natural or legal person with responsibility for design and/or manufacture of a *medical device* with the intention of making the *medical device* available for use, under his name; whether or not such a *medical device* is designed and/or manufactured by that person himself or on his 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 and/or manufacture", 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 and/or manufacture of that accessory is considered to be a *manufacturer*.

[SOURCE: ISO 14971:2019 [3], definition 3.9]

3.12
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 described in unique device identification (UDI). A UDI 'direct *marking*' is a type of *marking*.

Note 4 to entry: See Figure 1.

[SOURCE: ISO 20147:---- [15], definition 3.16]

3.13
medical device
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 and/or human tissues;

— devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016 [16], definition 3.11]

3.14
post-market surveillance

systematic process to collect and analyse experience gained from *medical devices* that have been placed on the market

[SOURCE: ISO 13485:2016 [16], definition 3.14]

3.15
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2019 [3], definition 3.18]

3.16
risk assessment
overall process comprising a *risk* analysis and a *risk* evaluation

[SOURCE: ISO 14971:2019 [3], definition 3.20]

3.17
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 20147:---- [15], definition 3.22]

3.18
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 20147:----[15], definition 3.25]

3.19
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 used again. This includes undergoing processing

[SOURCE: ISO 20147:---- [15], definition 3.26]

3.20
sterile
free from viable microorganisms

[SOURCE: ISO 20147:2020 [15], definition 3.28]

3.21

symbol
graphical representation appearing on the *label* (3.10) and/or associated documentation of a *medical device* that communicates *characteristic information* (3.4) 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).

3.22
title
unique name by which a graphical *symbol* is identified and referenced

[SOURCE: IEC 80416 -1:2008 [10], definition 3.9 – modified –replaced 'spoken of' with 'referenced'.]

4 General requirements

4.1 Proposal of *symbols* for adoption

a) *Symbols* proposed for adoption in this document (with the exception of symbols already registered under ISO 7000, ISO 7001 or IEC 60417) shall be validated in accordance with ISO 15223-2.

b) Any *symbol* proposed for adoption 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 identifies use of *symbols* as an appropriate method for conveying information essential for the proper use of a *medical device*, the *symbols* given in Table 1 may be marked on the *medical device*, appear on its packaging or in associated documentation.

NOTE ISO and IEC jointly 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/#search. This online collection 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. Various search and navigation facilities allow for easy retrieval of graphical *symbols.*

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

NOTE 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.

c) It is important that *symbols* be used properly. Guidance on the application of graphical *symbols* may be found in IEC 80416-3:2011. Before *symbols* are used, the *manufacturer* shall carry out a *risk assessment* that indicates that the use of the *symbol* does not introduce an unacceptable *risk*.

d) All dates and times presented in association with *symbols* shall use the conventions set out in ISO 8601-1:2019 and ISO 8601-2:2019.

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*.