



American
National
Standard

**ANSI/AAMI/
ISO 20417:
2021**

Medical devices—Information to be supplied
by the manufacturer

Medical devices—Information to be supplied by the manufacturer

Approved 18 December 2023 by
AAMI

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Abstract: This document specifies the requirements for information supplied by the manufacturer for a medical device or by the manufacturer for an accessory, as defined in 3.1. This document includes the generally applicable requirements for identification and labels on a medical device or accessory, the packaging, marking of a medical device or accessory, and accompanying information. This document does not specify the means by which the information is to be supplied.

Keywords: Medical devices, labels, manufacturer, accessory, medical device product, requirements

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Committee representation

Association for the Advancement of Medical Instrumentation

General Aspects Stemming from the Application of Quality Principles to Medical Devices Working Group

The adoption of ISO 20417:2021 as an American National Standard was initiated by the General Aspects Stemming from the Application of Quality Principles to Medical Devices Working Group (AAMI QM-WG02). AAMI QM-WG02 provides input to the ISO TC 210, Quality Management and Corresponding General Aspects for Products with a Health Purpose including Medical Devices, which is the responsible group for providing the U.S. input to the relevant group in ISO TC 210. U.S. representatives from AAMI QM-WG02 and the TAG played an active part in developing the ISO document.

At the time this document was published, the **General Aspects Stemming from the Application of Quality Principles to Medical Devices Working Group** has the following members:

Cochairs: Vacant

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of ISO 20417:2021

As indicated in the foreword to the main body of this document (page vii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed in ISO TC 210 as it is critical for medical device manufacturers and the ISO standard is recognized by the US FDA.

U.S. participation in ISO TC 210 is organized through the U.S. Technical Advisory Group, AAMI/Quality Management, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of Quality Management and Corresponding General Aspects for Products with a Health Purpose Including Medical Devices. Upon review of ISO 20417:2021, the AAMI/Quality Management Committee (QM) and the General Aspects Stemming from the Application of Quality Principles to Medical Devices Working Group (AAMI QM-WG02) decided to adopt it verbatim, as a first edition of ANSI/AAMI/ISO 20417:2021.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

“May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—Beginning with the ISO foreword on page vii, this American National Standard is identical to ISO 20417:2021

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/CLC) 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).

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.

This corrected version of ISO 20417:2021 incorporates the following corrections:

In 6.1.3. f):

If the *label* includes *symbols* or safety-related colours, they shall be explained in the *label*.

has been corrected to:

If the *label* includes *symbols* or safety-related colours, they shall be explained in the *instructions for use*.

Introduction

This document provides the requirements for the identification and *labels* on a *medical device* or *accessory*, the packaging, *marking* of a *medical device* or *accessory*, and *accompanying information*. The aim of this document is to serve as a central source of these common, generally applicable requirements, allowing each specific *product standard* or *group standard* to focus more concisely on the unique requirements for a *specific medical device* or group of *medical devices*.

The requirements of a *medical device product standard* or a *group standard* can make use of these general requirements. Where there is a conflict and a *product standard* or a *group standard* exists, this document should not be used separately. Specific requirements of medical device *product standards* or *group standards* take precedence over requirements of this document. Unless specified otherwise within a *product standard* or a *group standard*, the general requirements of this document apply.

Some *authorities having jurisdiction* have requirements that can differ from the requirements of this document.

This document has been prepared in consideration of:

- the application of *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*, IMDRF/GRRP WG/N47:2018^[3] on the *information supplied by the manufacturer* of a *medical device* (see Annex D);
- the application of *Labelling Principles for Medical Devices and IVD Medical Devices*, IMDRF/GRRP WG/N52:2019^[4] on the *information supplied by the manufacturer* of a *medical device* (see Annex E);
- the application of the *essential principles of safety and performance* on the *information supplied by the manufacturer* of a *medical device* according to ISO 16142-1:2016 (see Annex F);
- the application of the *essential principles of safety and performance* on the *information supplied by the manufacturer* of an *IVD medical device* according to ISO 16142-2:2017 (see Annex F);
- the general safety and performance requirements for the *information supplied by the manufacturer* of a *medical device* according to regulation (EU) 2017/745^[5] (see Annex G); and
- the general safety and performance requirements for the *information supplied by the manufacturer* of a *medical device* according to regulation (EU) 2017/746^[6] (see Annex H).

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.

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.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

Medical devices—Information to be supplied by the manufacturer

1 Scope

NOTE 1 There is guidance or rationale for this Clause contained in Clause A.2.

This document specifies the requirements for *information supplied by the manufacturer* for a *medical device* or by the *manufacturer* for an *accessory*, as defined in 3.1. This document includes the generally applicable requirements for identification and *labels* on a *medical device* or *accessory*, the packaging, *marking* of a *medical device* or *accessory*, and *accompanying information*. This document does not specify the means by which the information is to be supplied.

NOTE 2 Some *authorities having jurisdiction* impose different requirements for the identification, *marking* and documentation of a *medical device* or *accessory*.

Specific requirements of *medical device product standards* or *group standards* take precedence over requirements of this document.

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 codes*

ISO 3864-1:2011, *Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 8601-1, *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:—¹, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

¹ Under preparation. Stage at the time of publication: ISO/FDIS 15223-1:2021.

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+AMD1:2020, *Medical devices — Part 1: Application of the usability engineering process to medical devices*

ISO 80000-1, *Quantities and units — Part 1: General*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13485:2016, ISO 14971:2019, ISO 16142-1:2016, ISO 16142-2:2017 and IEC 62366-1:2015+AMD1:2020 as specified in Annex I and the following 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/>

NOTE An alphabetized index of defined terms used in this document is found in Annex I.

3.1

accessory

item, intended specifically by its *manufacturer*, to be used together with one or more *medical devices* to specifically enable or assist those *medical devices* to be used in accordance with their *intended use*

Note 1 to entry: An *accessory* is typically a consumable or separate item for use with one or more *medical devices*.

Note 2 to entry: Some *authorities having jurisdiction* consider an *accessory* to be a *medical device*.

Note 3 to entry: Some *authorities having jurisdiction* have a different definition of *accessory*.

3.2

accompanying information

information accompanying or *marked* on a *medical device* or *accessory* (3.1) 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.

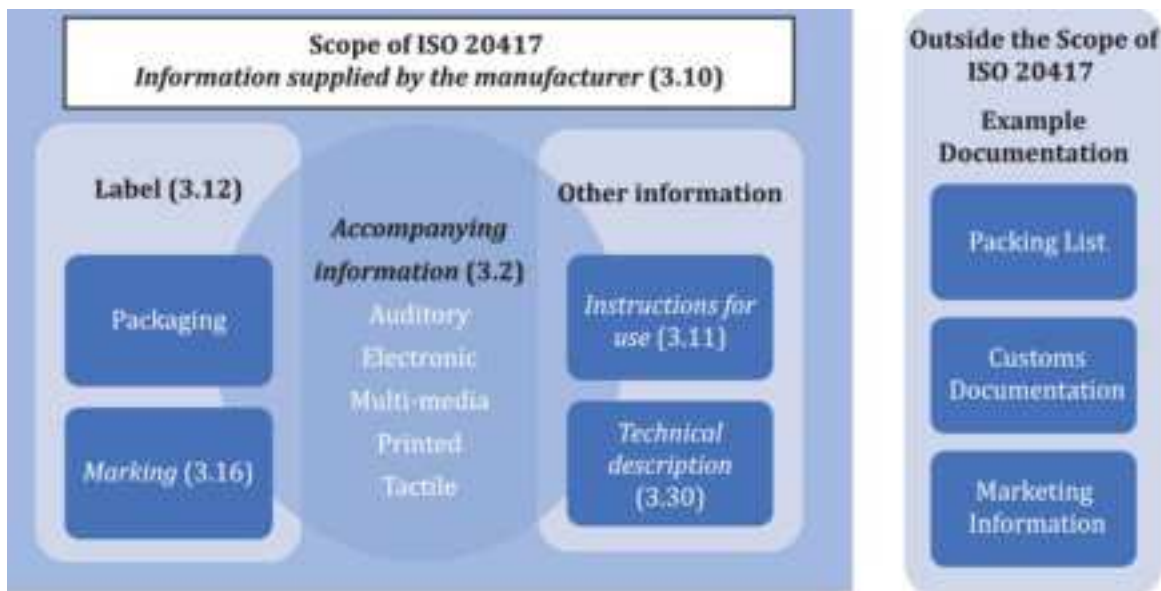


Figure 1 — Relationship of terms used to describe *information supplied by the manufacturer*

3.3

catalogue number

commercial product name

commercial product code

value given by the *manufacturer* to identify a specific *medical device* or *accessory* (3.1) as it relates to its form/fit, function and *process* (i.e., manufacturing *processes* requiring differentiation for the end user)

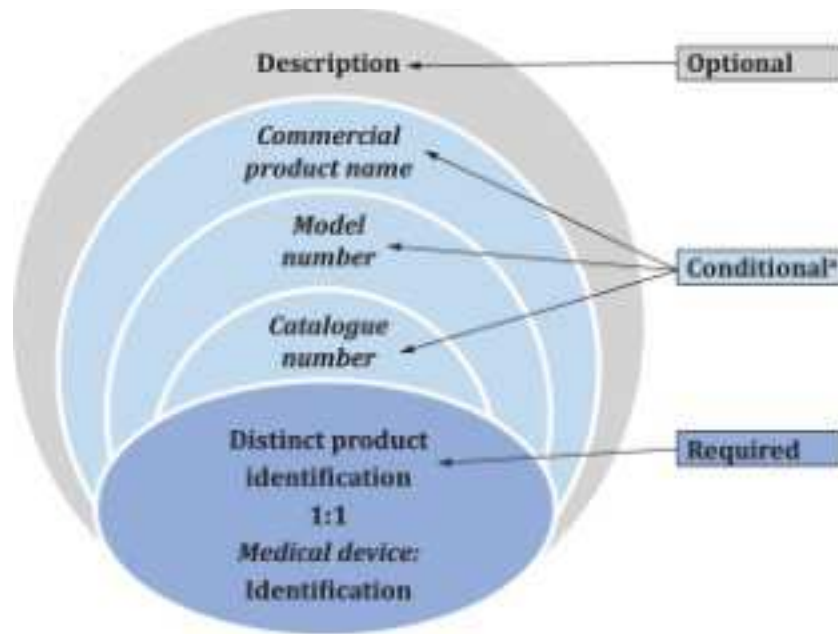
Note 1 to entry: A *catalogue number* shall consist of letters or numbers or a combination of these.

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 Figure 2.

[SOURCE: IMDRF/GRRP WG/N52:2019^[4], 3.2, modified — added 'or accessory' and Notes to entry.]



^a At least one of these conditional distinct product identifiers is required.

Figure 2 — Relationship of terms used to describe distinct product identification

3.4

clearly legible

easily legible

capable of being read by a person with normal vision

Note 1 to entry: There is guidance or rationale for this definition contained in Clause A.2.

[SOURCE: IEC 60601-1:2005+AMD1:2012^[2], 3.15, modified — Note 1 to entry added.]

3.5

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* (3.1) 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 13485:2016, 3.5^[7], modified — added 'or *accessory*' and Note 3 to entry.]

3.6

e-documentation

electronic documentation

any form of electronically accessible *information supplied by the manufacturer* (3.10) related to a *medical device* or *accessory* (3.1)

EXAMPLE CD/DVD-ROM, USB stick, website.

Note 1 to entry: See Figure 1.

3.7

expected lifetime

expected service life

time period specified by the *manufacturer* during which the *medical device* or *accessory* (3.1) is expected to remain safe and effective for use

Note 1 to entry: The *expected lifetime* can be affected by the *stability*.

Note 2 to entry: Maintenance, repairs or upgrades (e.g., safety or cybersecurity modifications) can be necessary during the *expected lifetime*.

Note 3 to entry: Some *medical devices* have an absolute lifetime (e.g., 5 y), whereas other *medical devices* (e.g., software) have a relative lifetime (e.g., the time between two major releases).

Note 4 to entry: There is guidance or rationale for this definition contained in Clause A.2.

[SOURCE: IEC 60601-1:2005+AMD1:2012^[2], 3.28, modified — added alternative term. The reference to 'me equipment or me system' has been replaced with '*medical device*', the parenthetical has been deleted and the notes added.]

3.8

importer

natural or legal person who imports a *medical device* or *accessory* (3.1) into a locale that was manufactured in another locale for the purposes of marketing

3.9

information for safety

information provided to the *user* or *responsible organization* as a *risk control* measure

EXAMPLE 1 Warnings, precautions or contraindications.

EXAMPLE 2 *Instructions for the use of a medical device or accessory to prevent use error or avoid a hazardous situation.*

EXAMPLE 3 Explanation of a safety feature of a *medical device*.

Note 1 to entry: *Information for safety* may be found in any or all types of *information supplied by the manufacturer*.

Note 2 to entry: *Information for safety* can be located on the display of a *medical device*.

3.10

information supplied by the manufacturer

information related to the identification and use of a *medical device* or *accessory* (3.1), 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.

Note 4 to entry: See Figure 1.

3.11

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* (3.1) 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 having jurisdiction*.

Note 5 to entry: See Figure 1.

3.12

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: IMDRF/GRRP WG/N52:2019^[4], 3.17, modified –added notes and replaced ‘unit’ and ‘devices’ with ‘item’.]

3.13

lay

lay person

individual who does not have formal education in a relevant field of healthcare or medical discipline and, if appropriate, relevant specialized training on the use of the specific *medical device*

3.14

lot

batch

defined amount of material or a number of *medical devices*, including finished product and *accessories* (3.1), that is manufactured in one *process* or a series of related *processes* and is intended to be homogenous

Note 1 to entry: A *lot* or *batch* is manufactured under essentially the same conditions and is intended to have uniform characteristics and quality within specified limits. A *lot* or *batch* is considered homogeneous when equivalent parts or materials are manufactured or

tested in the same manner, without interruption, typically on the same day or in the same time period, and produced by the same person or with the same machine/equipment set-up and fulfil the same quality specification.

Note 2 to entry: The defined amount of material or number of *medical devices* or *accessories* is normally associated with a unique statement of conformity to a defined quality specification.

3.15

lot number

batch code

batch number

lot code

production control containing a combination of letters or numbers associated with a single *lot* (3.14) or *batch* (3.14)

3.16

marking

information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *medical device* or *accessory* (3.1)

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 18113-1:2009^[8], 2.4, modified — replaced 'permanently' with 'durably', deleted notes and added Note 1 to entry and 'or accessory'.]

3.17

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* (3.1) or *medical device family* from another

Note 1 to entry: See Figure 2.

3.18

multiple patient multiple use

<*medical device*, *accessory*> intended by the *manufacturer* to be reused on multiple *patients* for multiple uses

Note 1 to entry: A *multiple patient multiple use medical device* or *accessory* typically requires *processing* between *patients*.

Note 2 to entry: A *multiple patient multiple use medical device* or *accessory* may require *processing* between uses on a single *patient*.

3.19

pictogram

simplified pictorial representation, used to guide people and tell them how to achieve a certain goal

[SOURCE: ISO/IEC TR 20007:2014^[9], 2.10]

3.20

processing

<preparation of *medical device*, *accessory*> activity to prepare a new or used *medical device* or *accessory* for its *intended use*

[SOURCE: ISO 11139:2018^[10], 3.214, modified — added 'or, accessory'.]

3.21

safety sign

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

[SOURCE: ISO 7010:2019^[11], 3.3]

3.22

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 14708-2:2012^[12], 3.20, modified — added 'production control containing a', replaced 'and/or' with 'or' and 'to distinguish a device from other devices with the same model designation' with 'for quality control and identification purposes to distinguish an individual *medical device* from other *medical devices* with the same *catalogue number* or *model number*'.]

3.23

service personnel

individuals or entity accountable to the *responsible organization* that install, assemble, maintain or repair a *medical device* or *accessory* (3.1)

[SOURCE: IEC 60601-1:2005^[2], 3.113, modified — The reference to 'me equipment, me systems or equipment' has been replaced by 'a *medical device* or *accessory*'.]

3.24

shelf-life

period of time until the expiry date during which a *medical device* or *accessory* (3.1) in its original packaging maintains its *stability* under the conditions specified in the *information supplied by the manufacturer*

[SOURCE: IMDRF/GRRP WG/N52:2019^[4], 3.36, modified — replaced 'by the manufacturer' with 'in the *information supplied by the manufacturer*'.]

3.25

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*.

3.26

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.

3.27

stability

<medical device, accessory> ability to maintain safety and performance characteristics within the specifications in information supplied by the manufacturer (3.10)

Note 1 to entry: *Stability* applies to:

- *medical devices* whose performance, physical, chemical or functional properties can be altered or compromised over a stated time interval;
- the period of time over which sterility is assured;
- IVD reagents, calibrators and controls, when stored, transported and used in accordance with conditions specified in the information supplied by the manufacturer
- reconstituted lyophilized materials, working solutions and material removed from sealed containers, when prepared, used and stored according to the information supplied by the manufacturer; and
- measuring instruments or measuring systems after calibration.

Note 2 to entry: *Stability* of an IVD reagent or measuring system is normally quantified with respect to time:

- in terms of the duration of a time interval over which a measured property changes by a stated amount; or
- in terms of the change of a property under specified conditions.

3.28

sterile

free from viable microorganisms

[SOURCE: ISO 11139:2018^[10], 3.271]

3.29

symbol

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

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 15223-1:—, 3.20]

3.30

technical description

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*.

Note 2 to entry: See Figure 1.

3.31

UDI carrier

unique device identification carrier

means to convey the UDI by using automatic identification and data capture (AIDC) and, if applicable, its human readable interpretation (HRI)

Note 1 to entry: *UDI carriers* can include 1D/linear bar code, 2D/Matrix bar code, RFID, etc.

[SOURCE: MDRF/UDI WG/N7:2013^[13]]

4 General considerations

- a) The *risk management process* of ISO 14971:2019 and the *usability engineering process* of IEC 62366-1:2015+AMD1:2020 should be used to determine the information, including *information for safety*, to be provided in the *information supplied by the manufacturer*.

NOTE *Medical device-specific standards can require additional information supplied by the manufacturer.*

- b) Where this document specifies a specific edition of a normatively referenced document, the *manufacturer* may substitute a more current version provided the *manufacturer* can demonstrate that the *residual risk* that results from the substitution remains acceptable and is comparable to the *residual risk* that results from applying the normatively referenced document.

- c) *Information supplied by the manufacturer* shall be in a language that is appropriate to the intended *user*.

NOTE 1 The choice of language of the *information supplied by the manufacturer* can be required by the *authority having jurisdiction*.

NOTE 2 More than one language can be required in some jurisdictions.

- d) The *accompanying information* shall specify any:

- 1) special skills, special training and special knowledge required of the intended *user* or the *responsible organization* that are necessary to be able to achieve the *intended use* of the *medical device*; and
- 2) if applicable, restrictions on the *use environment* that the *medical device* is intended to be used.

- e) The *information supplied by the manufacturer* shall be written and presented in terms that are readily understood by the intended *users*, taking into account their education, training and any special needs, as appropriate.

NOTE *Medical device-specific standards can require additional usability requirements.*

Check conformance by inspection of the information supplied by the manufacturer.

5 Information elements to be established

5.1 Units of measurement

- a) Numeric indications of parameters in the *information supplied by the manufacturer* shall be expressed in:

- 1) international system of units (SI) as specified in ISO 80000-1;
- 2) any other units required by a relevant *group standard* or *product standard*; or
- 3) any other units established by clinical convention.

- b) For application of SI units, their multiples and certain other units, ISO 80000-1 shall apply.

Check conformance by inspection of the information supplied by the manufacturer.

5.2 Graphical information

- a) Any graphical information that is replacing text such as *pictograms*, *symbols*, *safety signs* and safety-related identification colours used in the *information supplied by the manufacturer* shall have the meaning explained in the *accompanying documentation*.

NOTE Other requirements can be specified by the *authority having jurisdiction*.

- b) *Symbols* used in the *information supplied by the manufacturer* should be found in:

- 1) ISO 7000 (database);
- 2) ISO 7010;
- 3) ISO 15223-1;
- 4) IEC 60417 (database);
- 5) IEC/TR 60878:2015^[25]; or
- 6) if applicable:
 - i) relevant *product standards*; or
 - ii) relevant *group standards*.

- c) *Symbols* should be used in the *information supplied by the manufacturer*.

Check conformance by inspection of the information supplied by the manufacturer as well as the instructions for use or e-documentation.

5.3 Language and country identifiers

5.3.1 Language identifiers

In multilingual *information supplied by the manufacturer*, the language name used:

- a) should be clearly linked to the language used; and
- b) may be identified using:

- 1) the plain text name of the language; or

EXAMPLE 1 In an English section: 'English' or 'en' or 'eng'.

EXAMPLE 2 In a French section: 'Français' or 'fr' or 'fra'.

EXAMPLE 3 In a Russian section: 'Русский' or 'ru' or 'rus'.

- 2) the language codes given in

- i) ISO 639-1^[22],
- ii) ISO 639-2^[23], or

- iii) ISO 639-3^[24].

Check conformance by inspection of the information supplied by the manufacturer.

5.3.2 Country identifiers

Where contact details for multiple countries are provided in the *information supplied by the manufacturer*, the country shall be identified using:

- a) the country codes given in ISO 3166-1; or
- b) the plain text of the country name in a language of that country.

Check conformance by inspection of the information supplied by the manufacturer.

5.4 Dates

Any human-readable date, other than the text associated with the *UDI carrier*, in the *information supplied by the manufacturer* shall be expressed in accordance with ISO 8601-1 in the format:

NOTE Other requirements can be specified by the *authority having jurisdiction*.

- a) YYYY-MM-DD;
- b) YYYY-MM; or
- c) YYYY;

Check conformance by inspection of the information supplied by the manufacturer.

5.5 Full address

- a) Where this document refers to a full address, the address shall contain the following elements insofar as they are available in the address system of the locale where the relevant entity (*manufacturer, distributor, importer* or authorized representative) is physically located:
 - 1) street/road;
 - 2) number/house/floor;
 - 3) city;
 - 4) state/region;
 - 5) postal code; and
 - 6) country.
- b) The information regarding street/road and number/house/floor may be omitted if a postal code (corporate postal code) is used that fully replaces the indication of street/road and number/house/floor and is not a post office (PO) box number.

Check conformance by inspection of the information supplied by the manufacturer.

5.6 Commercial product name

A *medical device* may be identified with a *commercial product name* specific to the *medical device* or the *manufacturer*. A *commercial product name* is used to assist in the identification of a *medical device*.

5.7 Model number

- a) A *model number* may be used to represent a *medical device*, an *accessory* or a *medical device family* that have shared characteristics.
- b) A *model number* may be associated with multiple *catalogue numbers*.
- c) The *model number* may be identical to the *catalogue number*, when there is a single *catalogue number* represented by the *model number*.

5.8 Catalogue number

- a) A *medical device* or *accessory*, or a combination of *medical devices* or *accessories*, may be identified with a *catalogue number*.
- b) Each unique *catalogue number* shall be related to a single, defined product specification.
- c) Multiple *catalogue numbers* may be associated with a single *model number*.

Check conformance by inspection of the information supplied by the manufacturer.

5.9 Production controls

- a) A production control associated with a *medical device* shall be identified by at least one of the following:
 - 1) *lot number*;
 - 2) *serial number*;
 - 3) for *medical devices* containing cell tissues, donor identification information;
 - 4) year and month by which it is to safe to use; or
 - 5) year and month of manufacture.
- b) This information shall identify a controlled group of products associated with the production *process* for identification and traceability.

Check conformance by inspection of the information supplied by the manufacturer.

5.10 Unique device identifier

- a) Where necessary, a *medical device* or *accessory* shall be assigned a unique device identifier.

NOTE This can be required by the *authority having jurisdiction*,

- b) This identifier shall have a 1:1 relation to:
 - 1) a single *catalogue number*;

- 2) a single *model number*; or
- 3) a single *commercial product name*.

Check conformance by inspection of the information supplied by the manufacturer.

5.11 Types of use/reuse

A unique use classification shall be assigned at the level of *model number* or *catalogue number* from one of the following:

- a) *single use*;
- b) *single patient multiple use*; and
- c) *multiple patient multiple use*.

Check conformance by inspection of the information supplied by the manufacturer.

5.12 Sterile

- a) A *medical device* or *accessory* that is *sterile* shall be identified as *sterile*.
- b) A *sterile medical device* or *accessory* shall be identified with the method of sterilization.
- c) *Medical devices* or *accessories* available *sterile* and non-*sterile* shall have different:
 - 1) *model numbers*; or
 - 2) *catalogue numbers*.

Check conformance by inspection of the information supplied by the manufacturer.

6 Requirements for accompanying information

6.1 Requirements for information to be supplied on the *label*

6.1.1 Minimum requirements for the *label*

- a) The information required in 6.1 shall be provided as a *label*.
- b) The information on the *label* shall be provided in a human-readable format.
- c) The information required in 6.1 shall be provided as a *marking* unless:
 - 1) the size of the *medical device* or *accessory* does not allow fixation of this information on the *medical device* or *accessory*;
 - 2) the nature of the outer surfaces does not allow fixation of this information on the *medical device* or *accessory*;
or
 - 3) the omission of these *markings* does not adversely affect the *benefit/risk* balance according to ISO 14971:2019.

Check conformance by inspection of the label and, if appropriate, the marking or risk management file.

6.1.2 Identification of the *manufacturer*

- a) The *label* of a *medical device* or *accessory* shall include the name or trade name and, unless otherwise included in the *IFU*, the full address of
- 1) the *manufacturer*; and
 - 2) where necessary, if the *manufacturer* does not have an address within the locale, an authorized representative within the locale,
- to which the *responsible organization* can refer.

NOTE Item 2) can be required by the *authority having jurisdiction*.

- b) In locales where the *manufacturer* or their authorized representative is required to be registered, the address used shall be the same as the registered address.
- c) *Symbol* ISO 7000-3082 or *symbol* 5.1.1 from ISO 15223-1:— may be used to identify the *manufacturer*.
- d) *Symbol* 5.1.2 from ISO 15223-1:— may be used to identify the authorized representative.
- 1) When using *symbol* 5.1.2 from ISO 15223-1:—, the 'EC' may be replaced by the 2-letter or 3-letter country code given in ISO 3166-1.
 - 2) The address of the authorized representative may be applied by someone other than *manufacturer*.

EXAMPLE A *label* applied by the authorized representative and not the *manufacturer*.

- i) An additional *label* shall not obscure any information on the *label* provided by the *manufacturer*.
- e) The *medical device* or *accessory* may be *labelled* with the country of manufacture using either:
- 1) a text string; or
- EXAMPLE Made in CC (where CC is the country code from ISO 3166-1)
- 2) *symbol* IEC 60417-6049 or *symbol* 5.1.11 from ISO 15223-1:—.

Check conformance by inspection of the label.

6.1.3 Identification of the *medical device* or *accessory*

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

- a) The *label* of a *medical device* or *accessory* shall include all of the following
- 1) the details necessary for the *user* to identify:
 - i) the *medical device* or *accessory*; and
 - ii) its use.
- EXAMPLE 'Drug Eluting Stent' or 'Blood Glucose Meter' or 'Pulse Oximeter' or 'Infusion Pump'.
- 2) a distinctive identification.

- i) If a *model number* is used, it shall be identified by:
 - I) a text string; or

EXAMPLE For an English *label*: 'Model number xyz123' or 'model xyz123'.
 - II) *symbol* IEC 60417-6050.
 - ii) The *catalogue number* shall be identified by:
 - I) a text string; or

EXAMPLE For an English *label*: 'Catalogue number xyz123'.
 - II) *symbol* ISO 7000-2493 or *symbol* 5.1.6 from ISO 15223-1:—.
 - iii) If a *commercial product name* is used, it shall be expressed as a text string.
- b) The *medical device* or *accessory* shall be *labelled* with all of the following:
- 1) any special storage or handling conditions;
 - i) These special storage or handling conditions may be kept to a minimum.
 - ii) In this case, more detailed information should appear in the *instructions for use*.
 - 2) any special operating instructions that need to be brought to the immediate attention of the *user*; and
 - i) These special operating instructions may be kept to a minimum.
 - ii) In this case, more detailed information should appear in the *instructions for use*.
 - 3) any necessary warnings or precautions that need to be brought to the immediate attention of the *user*.
 - i) These warnings or precautions may be kept to a minimum, in which case, more detailed information should appear in the *instructions for use*.
- c) If the *medical device* or *accessory*, other than *IVD medical devices*, 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 shall be *labelled* as containing such substances.
- 1) The *symbol* ISO 7000-2725 or *symbol* 5.4.5 from ISO 15223-1:— may be used for latex.
 - 2) The *symbol* EN 15986:2011 may be used for phthalates.
 - 3) The *symbol* ISO 7000-3723 or *symbol* 5.4.10 from ISO 15223-1:— may be used for endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction substances.
 - 4) The *symbol* ISO 7000-2725 may be used for other substances.
- d) If applicable, the *medical device* or *accessory* shall be *labelled* with all the following:
- 1) an indication that electronic *instructions for use* are available, if some or all of the *instructions for use* are e-documentation;

- i) Electronic *instructions for use* may be indicated by
 - I) a text string indicating electronic *instructions for use*; or
 - II) *symbol* ISO 7000-1641 or *symbol* 5.4.3 of ISO 15223-1:—
 - 1. with an accompanying e-IFU indicator, or
 - 2. with a web address;
 - ii) Where applicable, the *label* shall include a reference to the accessibility or availability of this e-*documentation*.
 - iii) Where applicable, the *label* shall include the website address where the correct *instructions for use* can be consulted.
- 2) if intended for *single use*,
- i) a text string indicating 'do not reuse',
 - ii) a text string indicating 'single use only', or
 - iii) *symbol* ISO 7000-1051 or *symbol* 5.4.2 from ISO 15223-1:—;
- 3) if intended for *single patient multiple use*,
- i) a text string indicating 'single patient multiple use', or
 - ii) *symbol* ISO 7000-3706 or *symbol* 5.4.12 from ISO 15223-1:—;
- 4) if reuse is limited, the limitation on reuse;
- EXAMPLE The maximum number of allowable reuses or *processing* cycles.
- 5) as *sterile* and identify the method of sterilization;
- i) *Sterile* and the method of sterilization may be identified by:
 - I) a text string; or
 - II) as appropriate, with *symbol*
 - 1. ISO 7000-2500 or *symbol* 5.2.2 from ISO 15223-1:—,
 - 2. ISO 7000-2501 or *symbol* 5.2.3 from ISO 15223-1:—,
 - 3. ISO 7000-2502 or *symbol* 5.2.4 from ISO 15223-1:—,
 - 4. ISO 7000-2503 or *symbol* 5.2.5 from ISO 15223-1:—, or
 - 5. *symbol* 5.2.10 from ISO 15223-1:—.
- 6) as containing biological origin substances; and

- i) The *symbol* of ISO 7000-3701 or *symbol* 5.4.6 from ISO 15223-1:— may be used for containing human blood or plasma derivatives.
- ii) The *symbol* of ISO 7000-3699 or *symbol* 5.4.8 from ISO 15223-1:— may be used for containing biological material of animal origin.
- iii) The *symbol* of ISO 7000-3700 or *symbol* 5.4.9 from ISO 15223-1:— may be used for containing biological material of human origin.
- iv) The *label* should also include the quantity, proportion or strength of that substance if the substance will be in direct contact with the *patient*.

NOTE This can be required by the *authority having jurisdiction*.

7) as containing medicinal substances.

- i) The *symbol* of ISO 7000-3702 or *symbol* 5.4.7 from ISO 15223-1:— may be used for containing medicinal substances.
- ii) The *label* should also include the quantity, proportion or strength of that substance if the substance will be in direct contact with the *patient*.

NOTE This can be required by the authority having jurisdiction.

e) If containing nanotechnology materials, the *medical device* or *accessory* should be *labelled* with containing nanotechnology materials.

- 1) The *symbol* ISO 7000-3703 or *symbol* 5.4.11 from ISO 15223-1:— may be used for containing nanotechnology materials.

f) If the *label* includes *symbols* or safety-related colours, they shall be explained in the *instructions for use*.

Check conformance by inspection of the label.

6.1.4 Other *label* requirements

a) The *label* of a *medical device* or *accessory* shall include production controls, as applicable:

1) *lot number*;

i) The *lot number* may be identified by:

I) a text string; or

II) *symbol* ISO 7000-2492 or *symbol* 5.1.5 from ISO 15223-1:—.

2) *serial number*;

i) The *serial number* may be identified by:

I) a text string; or

II) *symbol* ISO 7000-2498 or *symbol* 5.1.7 from ISO 15223-1:—.

- 3) the year, month and day by which it is safe to use; or
 - i) The date by which it is safe to use may be identified by:
 - I) a text string; or
 - II) *symbol* ISO 7000-2607 or *symbol* 5.1.4 from ISO 15223-1:—.
- 4) the year, month and day of manufacture, for a *medical device* or *accessory* without a date by which it is safe to use.
 - i) The date of manufacture may be identified by:
 - I) a text string;
 - II) *symbol* ISO 7000-2497 or *symbol* 5.1.3 from ISO 15223-1:—; or
 - III) *symbol* ISO 7000-3082 or *symbol* 5.1.1 from ISO 15223-1:—.
 - ii) The date of manufacture may be included in the *lot number* or *serial number*.
- b) The *label* of a *medical device* or *accessory* shall include a unique device identifier (UDI).

NOTE This can be required by the *authority having jurisdiction*.

 - 1) If more than one machine readable AIDC is on the *label*, *symbol* 5.7.10 from ISO 15223-1:— shall be used to identify the *UDI carrier*.
 - 2) *Single use medical devices* or *accessories* need not be *marked* with a *UDI carrier*.
- c) If the *medical device* or *accessory* is *sterile*, the *label* of a *medical device* or *accessory* shall include the year, month and day:
 - 1) by which it is safe to use; or
 - i) The date by which it is safe to use may be identified by:
 - I) a text string; or
 - II) *symbol* ISO 7000-2607 or *symbol* 5.1.4 from ISO 15223-1:—.
 - 2) of manufacture, for a *medical device* or *accessory* without a date by which it is safe to use.
 - i) The date of manufacture may be identified by:
 - I) a text string;
 - II) *symbol* ISO 7000-2497 or *symbol* 5.1.3 from ISO 15223-1:—; or
 - III) *symbol* ISO 7000-3082 or *symbol* 5.1.1 from ISO 15223-1:—.
 - ii) The date of manufacture may be included in the *lot number* or *serial number*.
- d) The *label* of a *medical device* or *accessory* may include unique version identifier of the *label*.