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Medical devices — Information to be supplied by the manufacturer

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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*.

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

This document provides the requirements for the identification and labels on a medical device or accessory, their 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 D);

— 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 E);

— 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 following print types are used:

— Requirements and definitions: roman type.

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— *Conformance specifications and terms defined in Clause 3 of this document or as noted: italic type.*

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, 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.

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

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Medical devices — Information to be supplied by the manufacturer

1 * Scope

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*, their 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 Some *authorities with 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*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 16142-2:2017, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards*

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

IEC 62366-1:2015+AMD1:2019, *Medical devices — Part 1: Application of the usability engineering process to medical devices*

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

1) Under preparation. Stage at the time of publication: ISO/DIS 15223-1:2020.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7010:2019, ISO 13485:2016, ISO 14971:2019, ISO 15223-1, ISO 16142-1:2016, ISO 16142-2:2017 and IEC 62366-1:2015+AMD1:2019 as specified in Annex E 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 beginning in Annex I.

3.1
accessory
item, intended specifically by its *manufacturer*, to be used together with one or more *medical device*s 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: 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*.

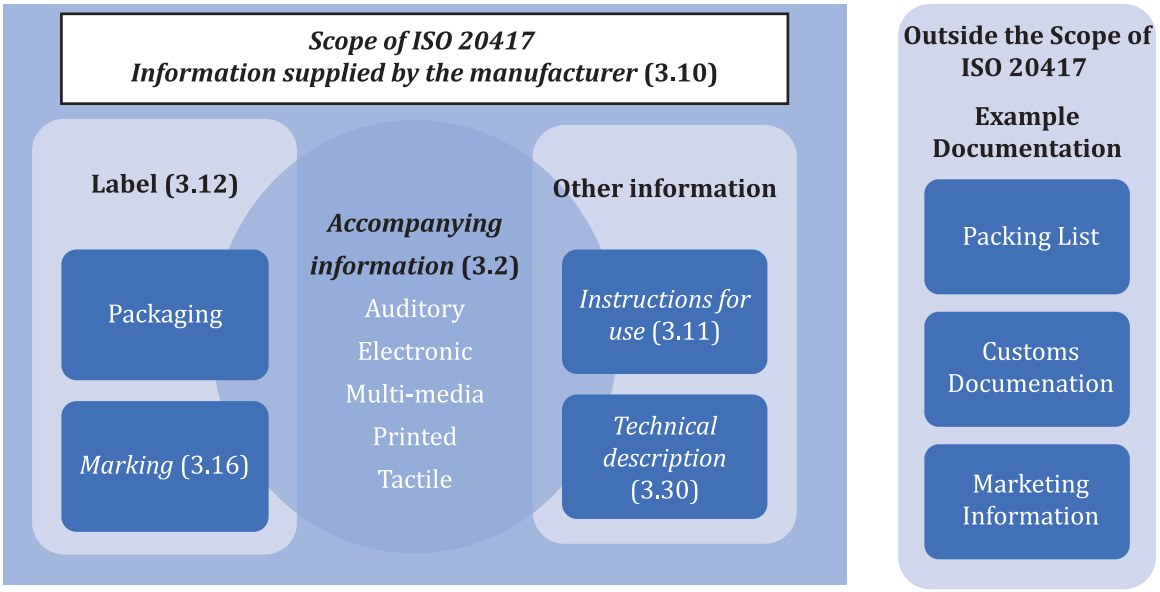
3.2
accompanying information
information accompanying or *marked* on a *medical device* or *accessory* (3.1) for the *user* or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the *medical device* or *accessory*, particularly regarding safe use

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 1 The *label* can include the information on the packaging of the *medical device*.

NOTE 2 *e-documentation* may include any or all types of *information supplied by the manufacturer* partially or entirely.

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.

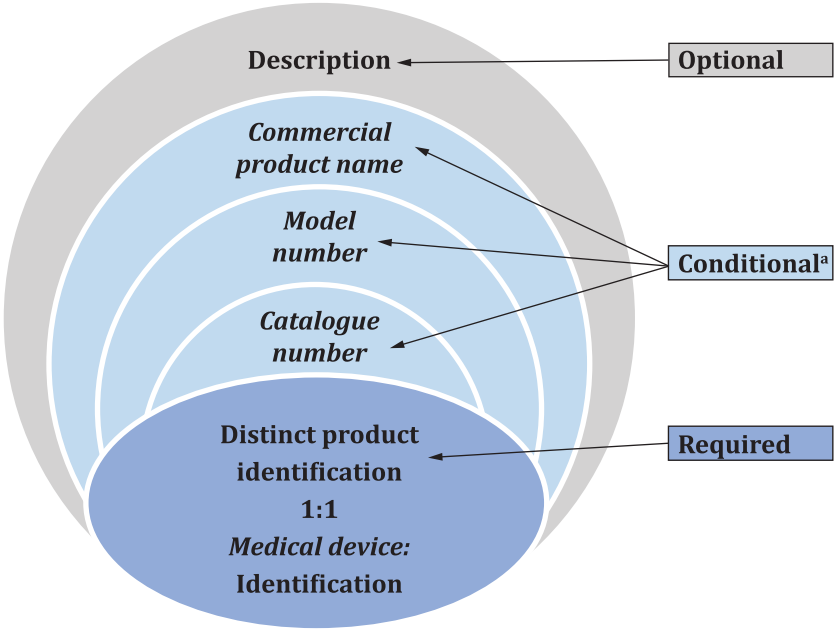
Note 2 to entry: For the purposes of this document, *commercial product code* should not be confused with the US FDA 'product code' or procode classification.

Note 3 to entry: See Figure 2.

[SOURCE: IMDRF/GRRP WG/52:2019, definition 3.2, modified — added 'or *accessory*' and Notes to entry.]

3.4
*** clearly legible**
easily legible
capable of being read by a person with normal vision

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.15]



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

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

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, modified — added 'or *accessory*' and note 3.]

3.6
e-documentation
electronic documentation
any form of electronically accessible *information supplied by the manufacturer* 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).

[SOURCE: IEC 60601-1:2005+A1:2012, 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* 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
all 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*.

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.

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: See Figure 1.

[SOURCE: IMDRF/GRRP WG/52:2019, definition 3.17, modified –added notes and replaced 'unit' and 'devices' with 'item'.]

3.13
***l*ay**
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* or *batch*

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, definition 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, definition 2.10]

3.20
processing
<preparation of *medical device*, *accessory*> activity to prepare a new or used healthcare product for its *intended use*

[SOURCE: ISO 11139:2018, definition 3.214, modified — added ‘, *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, definition 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, definition 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, definition 3.113, modified — The reference to ‘me equipment, me systems or equipment’ has been replaced by ‘a *medical device* or *accessory*’.]