Medical devices — Information to be supplied by the manufacturer
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
<td>v</td>
</tr>
<tr>
<td>Introduction</td>
<td>vi</td>
</tr>
<tr>
<td>1 Scope</td>
<td>1</td>
</tr>
<tr>
<td>2 Normative references</td>
<td>1</td>
</tr>
<tr>
<td>3 Terms and definitions</td>
<td>2</td>
</tr>
<tr>
<td>4 General considerations</td>
<td>9</td>
</tr>
<tr>
<td>5 Information elements to be established</td>
<td>10</td>
</tr>
<tr>
<td>6 Requirements for accompanying information</td>
<td>13</td>
</tr>
<tr>
<td>7 Other information that is required to be supplied with the medical device or accessory</td>
<td>33</td>
</tr>
<tr>
<td>Annex A (informative) Particular guidance and rationale</td>
<td>35</td>
</tr>
<tr>
<td>Annex B (informative) Example test method for assessing clearly legible</td>
<td>38</td>
</tr>
<tr>
<td>Annex</td>
<td>Title</td>
</tr>
<tr>
<td>-------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>C</td>
<td>Example test method for assessing durability</td>
</tr>
<tr>
<td>D</td>
<td>Cross reference between the document and the requirements considered</td>
</tr>
<tr>
<td>E</td>
<td>Reference to the IMDRF essential principles and labelling guidances</td>
</tr>
<tr>
<td>F</td>
<td>Reference to the essential principles</td>
</tr>
<tr>
<td>G</td>
<td>Reference to the general safety and performance requirements for medical devices</td>
</tr>
<tr>
<td>H</td>
<td>Reference to the general safety and performance requirements for IVD medical devices</td>
</tr>
<tr>
<td>I</td>
<td>Terminology — Alphabetized index of defined terms</td>
</tr>
<tr>
<td></td>
<td>Bibliography</td>
</tr>
</tbody>
</table>
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 15223-11, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
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

3 Terms and definitions


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

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 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 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

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 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 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


3.20  
**processing**

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


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’.]