International Standard

ISO 20417

# Medical devices — Information to be supplied by the manufacturer

*Dispositifs médicaux — Informations à fournir par le fabricant*

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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).

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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 products with a health purpose including medical devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 20417:2021), which has been technically revised.

The main changes are as follows:

— update of the normative references;

— deletion of the former informative Annexes D, F, G and H;

— addition of the term *'applicable policy'*;

— deletion of item b) in Clause 4, and of item d) 1) in 6.1.2.

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.

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# Introduction

This document provides general requirements for the identification and labelling of a *medical device* or *accessory* that appears on the packaging, is *marked* on the *medical device* or *accessory* and is contained in the *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 to simplify those documents. Additional specific product information requirements can be set out in specific *product standards* or *group standards*. Unless specified otherwise within a *product standard* or a *group standard*, the general requirements of this document apply.

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/N47:2024[24] 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/N52:2024[25] on the *information supplied by the manufacturer* of a *medical device* (see Annex D);

This document is organized in a structured manner. Clause 4 contains general *process* requirements. Clause 5 contains the information that needs to be established to support creating the *information supplied by the manufacturer* such as units of measurements, how to identify languages and countries and how to express dates and addresses. It also contains the requirements regarding the identification of *medical devices* and *accessories,* such as items like a *catalogue number*, unique identification of software version, production control identifier, a consistent indication of use/reuse and sterilization state. Clause 6 contains the requirements for the *accompanying information* of *medical devices* and *accessories*. This includes the requirements for the packaging, the *label* and *marking* of *medical devices* and *accessories,* as well as the *instructions for use* and *technical description*.

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.

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# Medical devices — Information to be supplied by the manufacturer

## 1 Scope

NOTE 1 There is guidance or rationale for this Clause in A.2.1.

This document specifies the requirements for *information supplied by the manufacturer* for a *medical device* or 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 code*

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

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

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

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 15223-1:2021/Amd 1:2025, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements — Amendment 1: Addition of defined term for authorized representative and modified EC REP symbols to not be country or region specific*

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

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 14971:2019 and the following apply.

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

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

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

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

**3.1**
**accessory**
item intended specifically by its *manufacturer* to be used together with one or more *medical devices* (3.23) 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* (3.4) consider an *accessory* to be a *medical device*.

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

Note 4 to entry: In general, spare parts are not considered *accessories*.

**3.2**
**accompanying information**
*information supplied by the manufacturer* (3.15) with or *marked* (3.22) on a *medical device* (3.23) or *accessory* (3.1) for the *user* (3.49) or *responsible organization* (3.33), particularly regarding safe use

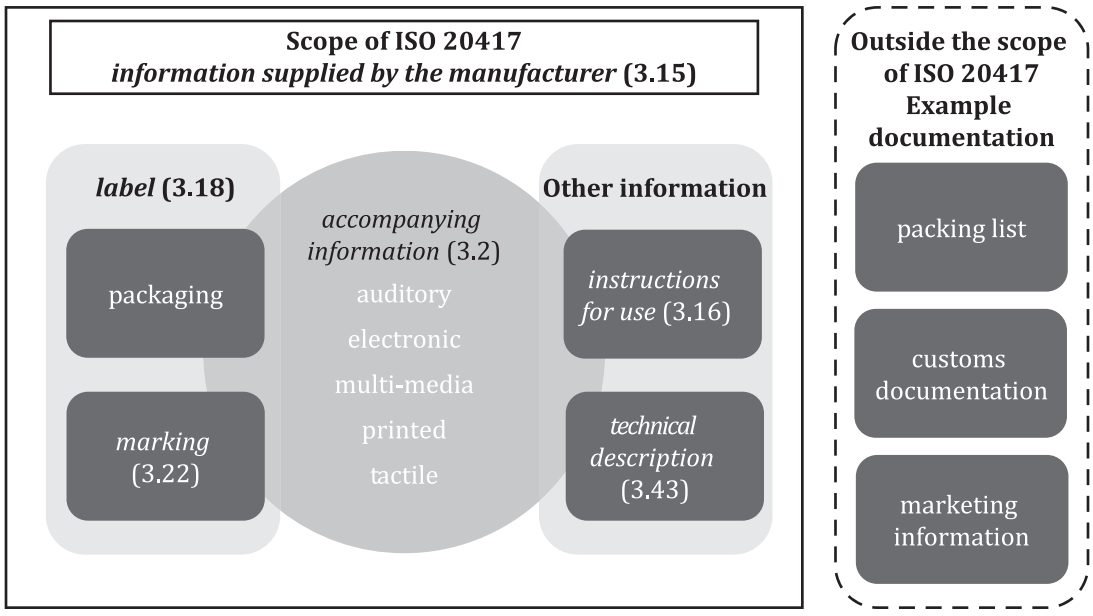
Note 1 to entry: The *accompanying information* is regarded as part of the *medical device* or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the *label* (3.18), *marking* (3.22), *instructions for use* (3.16), *technical description* (3.43), information shown on the packaging or graphical *user* interface (GUI), installation manual, quick reference guide, etc. and can address the installation, use, *processing* (3.31), maintenance and disposal of the *medical device* or *accessory*.

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

Note 4 to entry: *Medical devices* and *accessories* that can be used safely without *accompanying information* are exempted from having *accompanying information* by some *authorities having jurisdiction* (3.4).

Note 5 to entry: See Figure 1.




NOTE 1 The *label* (3.18) can include the information on the packaging of the *medical device* (3.23) or *accessory* (3.1).

NOTE 2 *e-documentation* (3.9) can include any or all types of *information supplied by the manufacturer* partially or entirely.

NOTE 3 'Marketing information' is also known as 'promotional material'.

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

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**3.3**
**applicable policy**
set of requirements relating to a product and its attributes such as form, fit, function, *process* or *information supplied by the manufacturer* (3.15)

Note 1 to entry: The *applicable policy* is established by the *authority having jurisdiction* (3.4).

Note 2 to entry: The *applicable policy* can include specification for the format of the *information to be supplied by the manufacturer*.

**3.4**
**authority having jurisdiction**
**AHJ**
regulatory authority
governmental agency or office assigned to oversee the regulation of a regulated product within a country, jurisdiction or assigned territory

**3.5**
**authorized representative**
*organization* (3.28) established within a country or jurisdiction who has received a written mandate from the *manufacturer* to act on their behalf for specified tasks regarding the latter's obligations under that country or jurisdiction's legislation

[SOURCE: ISO 13485:2016, 3.2, modified — "natural or legal person" was changed to "organization".]

**3.6**
**catalogue number**
**commercial product name**
**commercial product code**
reference number
reorder number
value given by the *manufacturer* to identify a specific *medical device* (3.23) or *accessory* (3.1) as it relates to its form, fit, function and *process*

Note 1 to entry: A *catalogue number* can relate to manufacturing *processes* requiring differentiation for the end *user* (3.49).

Note 2 to entry: A *catalogue number* only consists of letters or numbers or a combination of these.

Note 3 to entry: A *commercial product code* is different from the product coding of an *authority having jurisdiction* (3.4) (e.g. US FDA 'product code' or procode classification).

Note 4 to entry: See Figure 2.

Note 5 to entry: Adapted from Reference [23].

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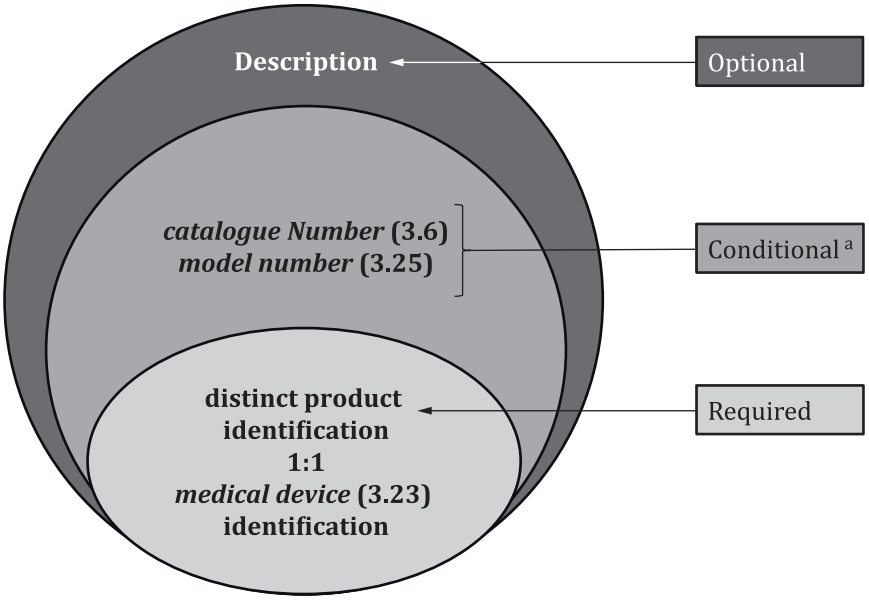


a At least one of these conditional distinct product identifiers is required.

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

**3.7**
**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 in A.2.2.

[SOURCE: IEC 60601-1:2005, 3.15, modified — Note 1 to entry replaced.]

**3.8**
**distributor**
*organization* (3.28), different from the *manufacturer* or *importer* (3.13), in the supply chain who, on their own behalf, furthers the availability of a product to the *user* (3.49)

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

Note 2 to entry: *Organizations* 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: Repackaging or otherwise changing the container, wrapper, or *accompanying information* (3.2) of the product package is not a distribution activity. *Distributers* can provide their identification on these items.

[SOURCE: ISO 13485:2016, 3.5, modified — In the definition, "different from the manufacturer or importer" was added, "natural or legal person" was changed to "*organization*" and "medical device" was changed to "product"; in Note 2 to entry "*person*" were changed to "*organization*"; Note 3 to entry was added.]

**3.9**
**e-documentation**
**electronic documentation**
form of electronically accessible *information supplied by the manufacturer* (3.15)

EXAMPLE 1 CD-ROM, DVD-ROM, USB stick, website or information accessible through an application programming interface (API), in the case that software that does not have a graphical *user* (3.49) interface (GUI).

EXAMPLE 2 Machine readable information such as a software bill of materials (SBOM).

Note 1 to entry: See Figure 1.

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**3.10**
**essential principles**
**essential principles of safety and performance**
fundamental high-level requirements that, when conformed with, ensure a *medical device* (3.23) or *accessory* (3.1) is safe and performs as intended

**3.11**
**expected lifetime**
**expected service life**
period specified by the *manufacturer* during which the product is expected to remain safe and effective for use

Note 1 to entry: The *expected lifetime* can be affected by the *stability* (3.40).

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 products have an absolute *expected lifetime* (e.g. 5 y) and some have an *expected lifetime* based on the number of uses or cycles (e.g. 15 uses) or duration of use, whereas other products (e.g. software) have a relative *expected lifetime* (e.g. the time between two major releases).

Note 4 to entry: There is guidance or rationale for this definition in A.2.3.

Note 5 to entry: Adapted from IEC 60601-1:2005, 3.28.

**3.12**
**group standard**
basic standard that specifies safety and performance criteria applicable to several or a family of similar products, *processes*, or services

Note 1 to entry: *Group standards* are sometimes referred to as semi-horizontal standards and usually apply to one field (sector).

[SOURCE: ISO 16142-1:2016, 3.4]

**3.13**
**importer**
*organization* (3.28) who imports a product that was manufactured in one locale into another locale for the purposes of marketing

**3.14**
**information for safety**
information provided to the *user* (3.49) or *responsible organization* (3.33) as a *risk control* measure

EXAMPLE 1 Warnings, precautions or contraindications.

EXAMPLE 2 *Instructions for the use* (3.16) of a *medical device* (3.23) or *accessory* (3.1) to prevent use error or avoid a *hazardous situation*.

EXAMPLE 3 Explanation of a safety feature of a product.

Note 1 to entry: *Information for safety* can be included in any or all types of *information supplied by the manufacturer* (3.15).

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

**3.15**
**information supplied by the manufacturer**
information related to the identification and use of a *medical device* (3.23) 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: *e-documentation* (3.9) is included in the *information supplied by the manufacturer.*

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Note 2 to entry: Shipping documents (e.g. packing list and customs documents) and promotional material are excluded from *information supplied by the manufacturer.* However, some *authorities having jurisdiction* (3.4) 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* or *accessory* and its *manufacturer*, and provide essential information about its safety, performance, and appropriate use.

Note 4 to entry: See Figure 1.

**3.16**
**instructions for use**
**IFU**
package insert
portion of the *accompanying information* (3.2) that is

— directed to the *user* (3.49), and

— essential for the safe and effective use of a *medical device* (3.23) or *accessory* (3.1)

Note 1 to entry: A *user* can be either a *lay* (3.19) *user* or professional *user* with relevant specialized training.

Note 2 to entry: Instructions for the professional *processing* (3.31) 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* (3.4).

Note 5 to entry: See Figure 1.

**3.17**
**IVD medical device**
**in vitro medical device**
*medical device* (3.23), whether used alone or in combination, intended by the *manufacturer* for the in vitro examination of specimens derived from the *patient* (3.29) solely or principally to provide information for diagnostic, monitoring or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

[SOURCE: ISO 14971:2019, 3.7, modified — The term "in vitro diagnostic medical device" was changed to "in vitro medical device"; in the definition, "device" was changed to "*medical device*" and "human body" to "*patient*".]

**3.18**
**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: The word *labelled* is used to designate the corresponding act.

Note 2 to entry: *Label* includes the *marking* (3.22) on the *medical device* (3.23) or *accessory* (3.1).

Note 3 to entry: Information indicated on a graphical *user* (3.49) interface (GUI) is considered as appearing on the item.

Note 4 to entry: See Figure 1.

Note 5 to entry: Adapted from Reference [25].

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**3.19**
**lay**, adj
lay person
not having formal education in a relevant field of healthcare or medical discipline and, if appropriate, not having relevant specialized training on the use of the specific *medical device* (3.23)

EXAMPLE *Lay user* (3.49), *lay responsible organization* (3.33).

**3.20**
**lot**
batch
defined amount of material or a defined number of *medical devices* (3.23), 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* is manufactured under essentially the same conditions and is intended to have uniform characteristics and quality within specified limits. A *lot* 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, are produced by the same person or with the same machine and 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.

**3.21**
**lot number**
**lot code**
batch code
batch number
production control identifier containing a combination of letters or numbers associated with a single *lot* (3.20)

**3.22**
**marking**
information, in text or graphical format, durably affixed, printed, etched or attached by equivalent means to a product

Note 1 to entry: The word *marked* is used to designate the corresponding act.

Note 2 to entry: *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.

Note 4 to entry: Adapted from ISO 18113-1:2022, 3.1.43.

**3.23**
**medical device**
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* to be used, alone or in combination, for *patients* (3.29), for one or more of the specific medical purpose(s) of

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

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

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

— supporting or sustaining life,

— control of conception,

— disinfection of *medical devices*,

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— providing information by means of in vitro examination of specimens derived from the *patient*,

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

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

— disinfection substances,

— aids for persons with disabilities,

— devices incorporating animal or human tissues,

— devices for in vitro fertilization or assisted reproductive technologies.

[SOURCE: ISO/IEC Guide 63:2019, 3.7, modified — "human being" and "human body" were changed to "*patient*".]

**3.24**
**medical device family**
group of *medical devices* (3.23) manufactured by or for the same *organization* (3.28) and having the same basic design and performance characteristics related to safety, *intended use* and function

[SOURCE: ISO 13485:2016, 3.12]

**3.25**
**model number**
model
letters, numbers or a combination of these assigned by a *manufacturer* to distinguish, by function or type, a particular *medical device* (3.23),*accessory* (3.1) or *medical device family* (3.24) from another

Note 1 to entry: See Figure 2.

**3.26**
**multiple patient multiple use**
<*medical device*, *accessory*> intended by the *manufacturer* to be reused on multiple *patients* (3.29) for multiple uses

Note 1 to entry: A *multiple patient multiple use medical device* (3.23) or *accessory* (3.1) typically requires *processing* (3.31) between *patients*.

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

**3.27**
**normal use**
operation, including stand-by, routine inspection and adjustments by any *user* (3.49), in accordance with the *accompanying information* (3.2) or, for those products provided without *accompanying information*, with generally accepted practice

Note 1 to entry: *Normal use* is different from *intended use*. While both include the concept of use as intended by the *manufacturer*, *intended use* focuses on the medical purpose while *normal use* incorporates not only the medical purpose, but maintenance, transport, *processing* (3.31), etc. as well.

Note 2 to entry: Use error can occur in *normal use*.

Note 3 to entry: Healthcare products that can be used safely without *accompanying information* are exempted from having *accompanying information* by some *authorities having jurisdiction* (3.4).

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.9, modified — in the definition, "*instructions for use*" was changed to "*accompanying information*"; in Note 3 to entry, "medical devices" was changed to "healthcare products".]

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**3.28**
**organization**
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: The concept of *organization* includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

[SOURCE: ISO 9000:2015, 3.2.1, modified — Note 2 to entry was deleted.]

**3.29**
**patient**
subject of care
living being receiving healthcare services

Note 1 to entry: Living being means person or animal.

Note 2 to entry: Healthcare services include diagnostic, therapeutic, monitoring, surgical or dental *procedures* and can be delivered in the home healthcare environment, professional healthcare environment, emergency medical services environment or a special environment.

Note 3 to entry: A *patient* can be a *user* (3.49).

Note 4 to entry: Safety limit values can be different for different *patients*, especially for animal *patients*.

Note 5 to entry: Adapted from IEC 60601-1:2005, 3.76.

**3.30**
**pictogram**
simplified pictorial representation

Note 1 to entry: A *pictogram* is used to guide people and tell them how to achieve a certain goal.

**3.31**
**processing**
<preparation of a healthcare product> *processes* to prepare a new or used healthcare product for its *intended use*

Note 1 to entry: *Processing* includes cleaning, disinfection and sterilization, as appropriate.

[SOURCE: ISO 17664-2:2021, 3.10, modified — “activity” was changed to “processes”; Note 1 to entry was changed.]

**3.32**
**product standard**
standard that specifies necessary safety and performance requirements for a specific or a family of product(s), *process(es)*, or service(s) making reference, as far as possible, to basic standards and *group standards* (3.12)

Note 1 to entry: *Product standards* are sometimes referred to as vertical standards.

**3.33**
**responsible organization**
*organization* (3.28) accountable for the installation, use, *processing* (3.31), maintenance, decommissioning or disposal of a *medical device* (3.23), *accessory* (3.1) and their detachable parts

Note 1 to entry: The *responsible organization* includes those individuals performing the activities for the *responsible organization* including the preparation of the infrastructure needed to support the installation.

Note 2 to entry: The *responsible organization* can be, for example, a hospital, an individual healthcare professional provider or a *lay person* (3.19) *user* (3.49). In home use applications, the *patient* (3.29), *user* and *responsible organization* can be one and the same person.

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Note 3 to entry: Education and training are included in "use".

Note 4 to entry: Adapted from IEC 60601-1:2005, 3.101.

**3.34**
**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 *symbol* (3.42), gives a particular safety message

[SOURCE: ISO 7010:2019, 3.3. modified — "graphical symbol" was changed to "symbol".]

**3.35**
**serial number**
production control identifier containing a combination of letters or numbers, selected by the *manufacturer*, intended for quality control and identification purposes to uniquely distinguish an individual product from other products with the same *catalogue number* (3.6) or *model number* (3.25)

Note 1 to entry: Adapted from ISO 14708-2:2019, 3.18.

**3.36**
**service personnel**
*organization* (3.28) accountable to the *responsible organization* (3.33) for the installation assembly, maintenance or repair a *medical device* (3.23) or *accessory* (3.1) and their detachable parts

Note 1 to entry: Adapted from IEC 60601-1:2005, 3.113.

**3.37**
**shelf-life**
period during which a product in its original packaging maintains its *stability* (3.40) under the conditions specified in the *information supplied by the manufacturer* (3.15)

Note 1 to entry: Adapted from Reference [25].

**3.38**
**single patient multiple use**
<*medical device*, *accessory*> intended by the *manufacturer* to be reused on an individual *patient* (3.29) for multiple uses

Note 1 to entry: A *single patient multiple use medical device* (3.23) or *accessory* (3.1) can require *processing* (3.31) between uses.

Note 2 to entry: For an implantable *medical device*, the duration from implanting to explanting the *medical device* is considered *single use* (3.39) and not *single patient multiple use.*

**3.39**
**single use**
**do not reuse**
use only once
<*medical device*, *accessory*> intended by the *manufacturer* to be used on an individual *patient* (3.29) or an individual specimen during a single *procedure* and then disposed of

Note 1 to entry: A *single use medical device* (3.23) or *accessory* (3.1) is not intended by its *manufacturer* to be further processed and used again.

Note 2 to entry: For an implantable *medical device*, the duration from implanting to explanting the *medical device* is considered *single use* and not *single patient multiple use* (3.38).

**3.40**
**stability**
<*medical device*, *accessory*> ability to maintain safety and performance characteristics within the specifications found in *information supplied by the manufacturer* (3.15)

Note 1 to entry: *Stability* applies to:

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— *medical devices* (3.23) whose performance, physical, chemical or functional properties can be altered or compromised over a stated time interval;

— the period over which sterility is assured;

— in vitro diagnostic (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*;

— 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 time interval over which a measured property changes by a stated amount; or

— in terms of the change of a property under specified conditions.

**3.41**
**sterile**
free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.271]

**3.42**
**symbol**
graphical representation appearing on the *label* (3.18) or in *accompanying information* (3.2) of a product 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 representation, a graphical representation, or one that uses familiar objects, including alphanumeric characters (with sufficient justification).

**3.43**
**technical description**
portion of the *accompanying information* (3.2) that is

— directed to the *responsible organization* (3.33) and *service personnel* (3.36), and

— essential for installation, preparation for the first use and safe use, maintenance or repair, as well as *processing* (3.31), transport or storage for the *expected lifetime* (3.11) including decommissioning or disposal of a *medical device* (3.23) or *accessory* (3.1)

Note 1 to entry: The *technical description* can be included in the *instructions for use* (3.16).

Note 2 to entry: See Figure 1.

**3.44**
**UDI carrier**
**unique device identification carrier**
means to convey the unique device identification (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.

Note 2 to entry: Adapted from Reference [26].

**3.45**
**usability**
characteristic of the *user* (3.49) interface that facilitates use and thereby establishes use effectiveness, use efficiency and *user* satisfaction in the intended *use environment* (3.47)

Note 1 to entry: All aspects of *usability*, including use effectiveness, use efficiency and *user* satisfaction, can either increase or decrease safety.

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[SOURCE: IEC 62366-1:2015, 3.16, modified — added “use” in front of “effectiveness” and “efficiency”.]

**3.46**
**usability engineering**
human factors engineering
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of products and *user* (3.49) tasks to achieve adequate *usability* (3.45)

Note 1 to entry: Achieving adequate *usability* can result in acceptable *risk* related to use.

Note 2 to entry: *Products* include *medical devices* (3.23), *accessories* (3.1) and health software.

[SOURCE: IEC 62366-1:2015, 3.17, modified — “medical devices (including software) systems and tasks” was changed to “product and user tasks”; Note 2 was added.]

**3.47**
**use environment**
actual conditions and setting in which *users* (3.49) interact with a product

Note 1 to entry: The conditions of use or attributes of the *use environment* can include hygienic requirements, frequency of use, location, lighting, noise, temperature, mobility and degree of internationalization. Social attributes such as team versus individual, chaotic versus calm, stress level and length of shift can also play a role.

[SOURCE: IEC 62366-1:2015, 3.20, modified — “the medical device” was changed to “a product”; the second sentence was added in Note 1 to entry.]

**3.48**
**use specification**
description of the important characteristics related to the context of use of a product

Note 1 to entry: The intended medical indication, *patient* (3.29) population, part of the body or type of tissue interacted with, *user* (3.49) profile, *use environment* (3.47) and operating principle are typical elements of the *use specification*.

Note 2 to entry: The summary of the *use specification* is referred to by some *authorities having jurisdiction* (3.4) as the ‘statement of intended use’.

Note 3 to entry: The *use specification* is an input to determining the *intended use*.

[SOURCE: IEC 62366-1:2015, 3.23, modified — The admitted term “application specification” was removed; “summary” was changed to “description”; the reference to ISO 14971 was removed from Note 3.]

**3.49**
**user**
person operating, handling or interacting with the product

Note 1 to entry: There can be more than one *user* of a product.

Note 2 to entry: Common *users* include healthcare professional providers, *patients* (3.29), *lay* (3.19) caregivers, processors and *service personnel* (3.36).

Note 3 to entry: Adapted from IEC 62366-1:2015, 3.24.

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

b) *Information supplied by the manufacturer* shall be in a language that:

1) is appropriate to the intended *user*;

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