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Medical devices — Information to be supplied by the manufacturer

Dispositifs médicaux — Informations à fournir par le fabricant

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

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Foreword

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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*

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*

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

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 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*.

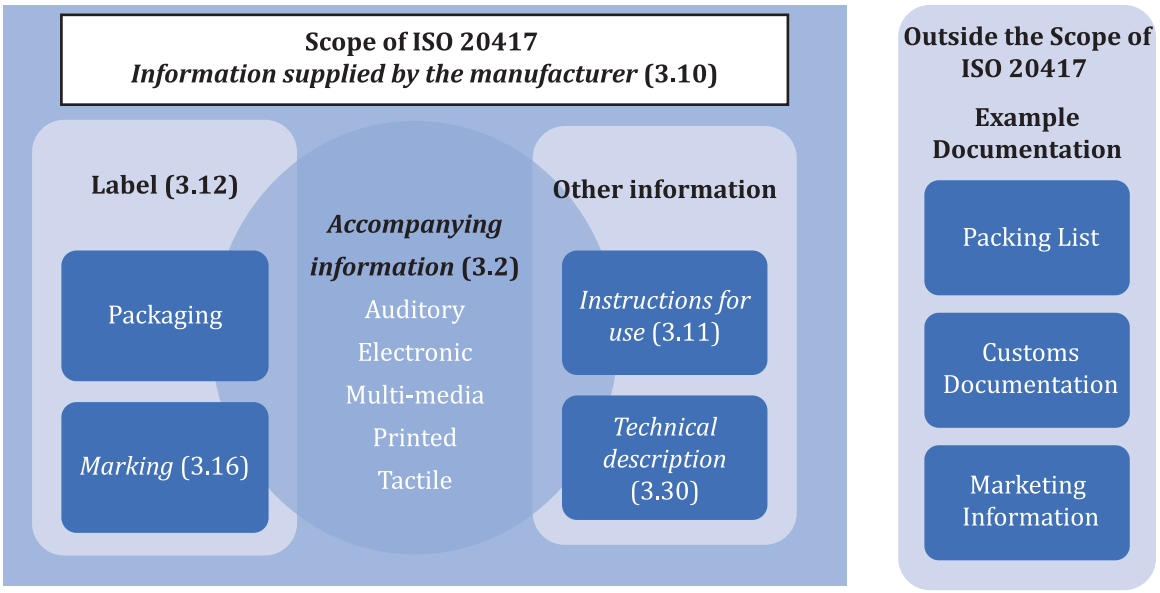
3.2
accompanying information
information accompanying or *marked* on a *medical device* or *accessory* (3.1) for the *user* or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the *medical device* or *accessory*, particularly regarding safe use

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 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*)

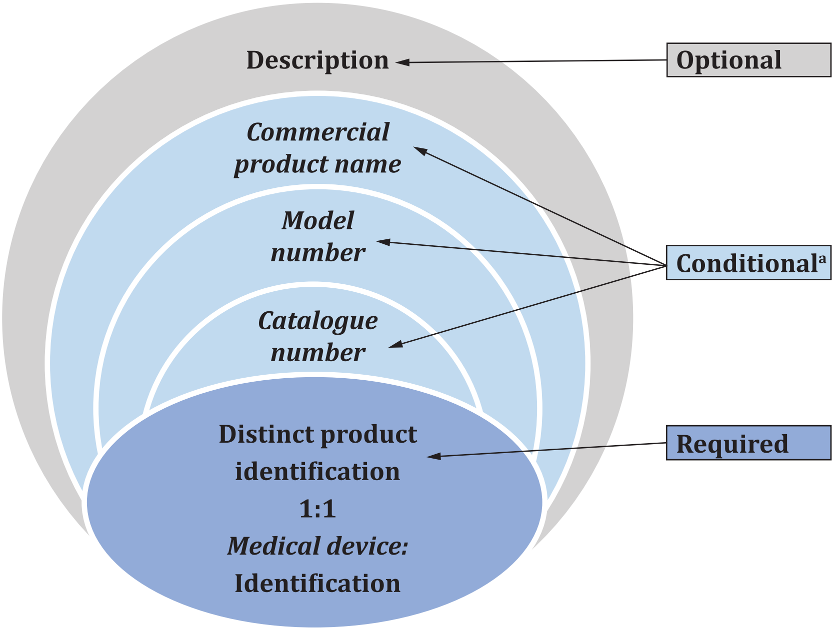
Note 1 to entry: A *catalogue number* shall consist of letters or numbers or a combination of these.

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
***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* (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.