SLOVENSKI STANDARD
oSIST prEN ISO 20417:2025

01-januar-2025

Medicinski pripomočki - Informacije, ki jih zagotovi proizvajalec (ISO/DIS 20417:2024)

Medical devices - Information to be supplied by the manufacturer (ISO/DIS 20417:2024)

Medizinprodukte - Anforderungen an vom Hersteller bereitzustellende Informationen (ISO/DIS 20417:2024)

Dispositifs médicaux - Informations à fournir par le fabricant (ISO/DIS 20417:2024)

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ICS:

01.110	Tehnična dokumentacija za izdelke	Technical product documentation
11.040.01	Medicinska oprema na splošno	Medical equipment in general

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DRAFT International Standard

ISO/DIS 20417

Medical devices — Information to be supplied by the manufacturer

Dispositifs médicaux — Informations à fournir par le fabricant

ICS: 11.040.01

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ISO/TC **210**

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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).

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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 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).

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

The main change are as follows:

— updated the normative references;

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

— addition of the concept of *applicable policy*; and

— deletion of 4 b) and 6.1.2.d) 1).

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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[21] 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[22] on the *information supplied by the manufacturer* of a *medical device* (see Annex D);

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 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

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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 7010:2019, *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+AMD1[1)], *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*

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 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 https://www.electropedia.org/

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

1) Under preparation. Stage at the time of publication: ISO/DAMD1 ISO 15223-1:2024.

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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* (3.4) 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) accompanying or *marked* (3.22) on a *medical device* (3.23) or *accessory* (3.1) for the *user* (3.50) or those accountable for the installation, use, *processing* (3.31), 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* (3.18), *marking* (3.22), *instructions for use* (3.16), *technical description* (3.43), installation manual, quick reference guide, etc. and can address the installation, use, *processing* (3.31), maintenance, decommissioning and disposal of the *medical device* or *accessory*

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.

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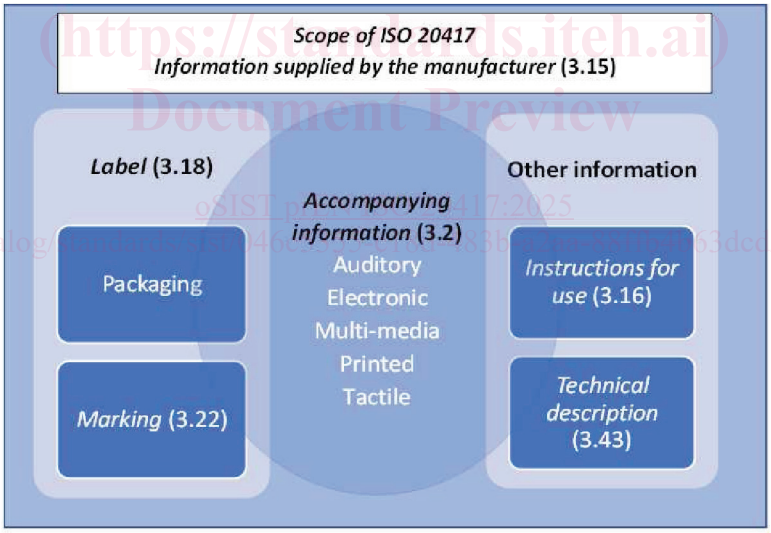

NOTE 1 The *label* (3.18) can include the information on the packaging of the *medical device* (3.23).

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 the *medical device* (3.23) or *accessory* (3.1) and its attributes such as form, fit, function, *process* or *information to be supplied by the manufacturer* (3.15)

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

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

3.4
authority having jurisdiction
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
natural or legal person established within a country or jurisdiction who has received a written mandate from the *manufacturer* to act on his behalf for specified tasks regarding the latter's obligations under that country or jurisdiction's legislation

[SOURCE: ISO 13485:2016, 3.2, modified — replaced "with regard to" with "regarding".]

3.6
catalogue number
commercial product name
commercial product code
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* (i.e., manufacturing *processes* requiring differentiation for the end *user* (3.50))

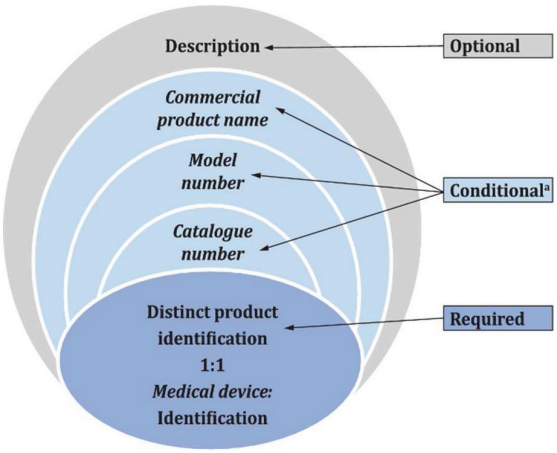
Note 1 to entry: A *catalogue number* shall consist of letters or numbers or a combination of these.

Note 2 to entry: A *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,[22] 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

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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 contained in Clause A.2.

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

3.8
distributor
natural or legal person, different from the *manufacturer* or *importer* (3.14), in the supply chain who, on their own behalf, furthers the availability of a *medical device* (3.23) or *accessory* (3.1) to the *user* (3.50)

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

Note 2 to entry: 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* (3.2) 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 to entry.]

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

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

Note 1 to entry: See Figure 1.

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3.10
essential principles of safety and performance
essential principles
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 *medical device* (3.23) 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* (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 *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, 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.]

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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).

3.13
importer
natural or legal person who imports a *medical device* (3.23) or *accessory* (3.1) that was manufactured in one locale into another locale for the purposes of marketing

3.14
information for safety
information provided to the *user* (3.50) 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* (3.48) or avoid a *hazardous situation*.

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

Note 1 to entry: *Information for safety* may be found 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 *medical device*.

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 *information supplied by the manufacturer.*

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.*

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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) directed to the *user* (3.50) that is 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.

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3.17
in vitro medical device
IVD 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 — replaced "device" with "*medical device*" and "human body" with "*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 interface (GUI) is considered as appearing on the item.

Note 4 to entry: See Figure 1.

[SOURCE: IMDRF/GRRP WG/N52:2019,[22] 3.17, modified –added notes and replaced 'unit' and 'devices' with 'item'.]

3.19
lay, adj
lay person
not having 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* (3.23)

EXAMPLE *Lay user* (3.18), *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, 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.

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

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