SLOVENSKI STANDARD
oSIST prEN ISO 20417:2019

01-maj-2019

Medicinski pripomočki - Informacije, ki jih pridobi proizvajalec (ISO/DIS 20417:2019)

Medical Devices - Information to be provided by the manufacturer (ISO/DIS 20417:2019)

Medizinprodukte - Anforderungen an allgemeine Informationen des Herstellers (ISO/DIS 20417:2019)

Dispositifs médicaux - Informations à fournir par le fabricant (ISO/DIS 20417:2019)

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oSIST prEN ISO 20417:2019 **en**

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Medical devices — Information to be provided by the manufacturer

Dispositifs médicaux — Informations à fournir par le fabricant

ICS: 11.040.01

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Contents

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. 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. 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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

ISO 20417 was prepared by a Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This is the first edition of ISO 20417.

ISO 20417 replaces EN 1041 [1] [1].

1 Numbers in square brackets refer to the Bibliography.

Introduction

This standard provides the common, generic requirements for the design and implementation of *labels* on *medical devices* or their packaging, *marking* of *medical devices* or *accompanying documentation*.

This document is intended to replace or supplement the often-repetitive labelling requirements that are common among the existing *product standards* of *medical devices*. The aim of this document is to serve as a central source of these common, generic requirements, allowing each specific *product standard* in the future to focus more concisely on the unique requirements for a specific *medical device*.

The requirements of a *medical device*-specific *product standard* either supplement or modify these general requirements. Where a *product standard* exists, this document should not be used separately. Unless specified otherwise within a *product standard*, the general requirements of this document apply.

This document has been prepared to support the *essential principles of safety and performance* for the *information supplied by the manufacturer* of a *medical device* according to ISO 16142 (series).

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.

— *Test 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 Annex H of the 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.

Annex B contains a compendium of the symbols and safety signs referenced in this document.

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 provided by the manufacturer

1 * Scope

This document specifies the requirements for *information supplied by the manufacturer* for a *medical device* or *accessory*, as defined in 3.1. This document includes the generally applicable requirements for identification, *marking* and documentation of a *medical device* or *accessory*. This document does not specify the language to be used for such information, nor does it specify the means by which the information is to be supplied.

This document has been prepared to support:

— the *essential principles of safety and performance* for the information supplied by the *manufacturer* of a *medical device* according to ISO 16142-1:2016 (see Annex C); and

— the *essential principles of safety and performance* for the information supplied by the *manufacturer* of an *IVD medical device* according to ISO 16142-2:2017 (see Annex C);

— IMDRF/GRRP WG/N47:2018 [3] (see Annex D); and

— IMDRF/GRRP WG/N52:— [4] (see Annex D).

NOTE Some *authorities with jurisdiction* impose additional requirements for the identification, *marking* and documentation of a *medical device* or *accessory*.

The requirements of a *medical device*-specific *product standard* take priority over this document.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

NOTE 2 Informative references are listed in the bibliography.

ISO/IEC 646, *Information technology – ISO 7-bit coded character set for information interchange*

ISO 639-1:2002, *Codes for the representation of names of languages – Part 1: Alpha-2 Code*

ISO 639-2:1998, *Codes for the representation of names of languages – Part 2: Alpha-3 code*

ISO 639-3:2007, *Codes for the representation of names of languages – Part 3: Alpha-3 code for comprehensive coverage of languages*

ISO 3166-1:2013, *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 7000:2014, *Graphical symbols for use on equipment – Registered symbols*

ISO 7010:2011, *Graphical symbols – Safety colours and safety signs – Registered safety signs*
+Amendment 1:2012
+Amendment 2:2012
+Amendment 3:2012
+Amendment 4:2013
+Amendment 5:2014
+Amendment 6:2014
+Amendment 7:2016
+Amendment 8:2017
+Amendment 9:2018

ISO 8601:2004, *Data elements and interchange formats – Information interchange – Representation of dates and times*

ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes*

ISO 14971:—[2] (ed 2), *Medical devices – Application of risk management to medical devices*

ISO 15223-1:2016, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied –Part 1: General requirements*

ISO 15459-2, *Information technology – Automatic identification and data capture techniques – Unique identification – Part 2: Registration procedures*

ISO 15459-4, *Information technology – Automatic identification and data capture techniques – Unique identification – Part 4: Individual products and product packages*

ISO 15459-6, *Information technology – Automatic identification and data capture techniques – Unique identification – Part 6: Groupings*

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*

ISO 22742:2010, *Packaging – Linear bar code and two-dimensional symbols for product packaging*

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

IEC 62366-1:2015+AMD1:—[3], *Medical devices – Part 1: Application of the usability engineering process to medical devices*

ISO 80000-1:2009, *Quantities and units – Part 1: General*

[2] Under preparation. Stage at the time of publication: ISO FDIS 14971:2019.

[3] Under preparation. Stage at the time of publication: IEC DAMD 62366-1:2019.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7010:2011, ISO 13485:2016, ISO 14971:—, ISO 16142-1:2016, ISO 16142-2:2017 and IEC 62366-1:2015+AMD1:— and the following definitions apply.

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

3.1
accessory
item used together with one or more *medical devices* to enable or assist a *medical device* to be used in accordance with its *intended use*

Note 1 to entry: Some *authorities having jurisdiction* consider an *accessory* to be a *medical device*.

3.2
accompanying information
information accompanying or on a *medical device* or *accessory* and containing information for the *user* or those accountable for the installation, use, 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 *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.

3.3
catalogue number
product code
letters, numbers or a combination of these assigned by a *manufacturer* for ordering one or more *medical devices* or *accessories*

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

[SOURCE: IEC 60601-1:2005+AMD1:2012 [2], definition 3.15]

3.5
distributor
natural or legal person in the supply chain who, on his own behalf, furthers the availability of a *medical device* or *accessory* 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*.

[SOURCE: ISO 13485:2016 [14], definition 3.5, modified –added 'or *accessory*']

3.7

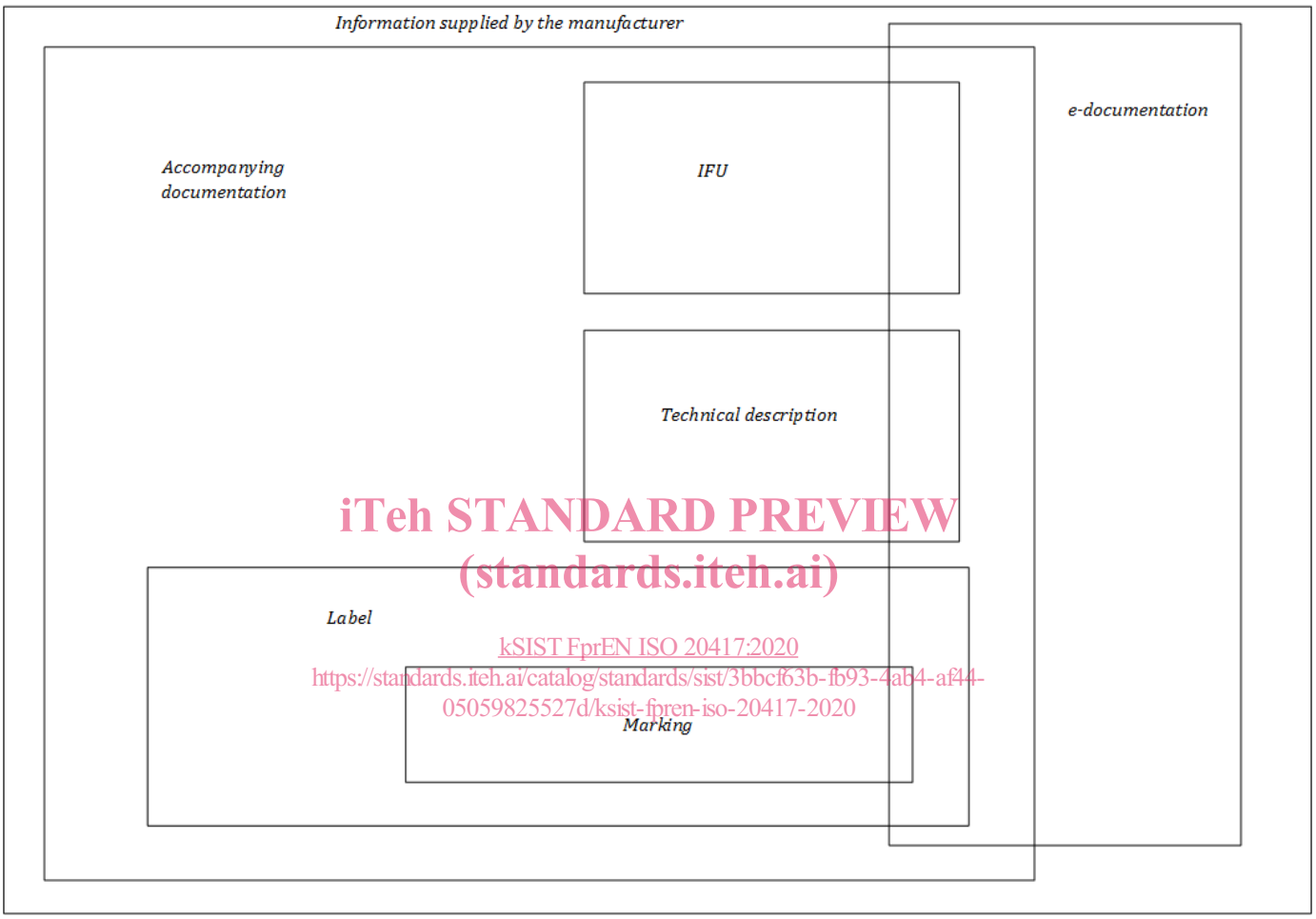
e-documentation

electronic documentation

any form of electronically accessible *information supplied by the manufacturer* related to a *medical device*

EXAMPLE CD/DVD-ROM, Internet or other mode

Note 1 to entry: See Figure 1.



NOTE The *label* includes the packaging of the *medical device*.

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

3.8

expected lifetime

expected service life

time period specified by the *manufacturer* during which the *medical device* or *accessory* is expected to remain safe 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*.

[SOURCE: IEC 60601-1:2005+A1:2012, definition 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.]

3.9
importer
natural or legal person in the supply chain who is the first in a supply chain to make a *medical device* or *accessory*, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed

[SOURCE: ISO 13485:2016 [14], definition 3.7, modified –added 'or *accessory*']

3.10
information for safety
information provided to the *user* or *responsible organization* that is used as a *risk control* measure

EXAMPLE 1 Warnings, precautions or contraindications.

EXAMPLE 2 Instructions in 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* can be located on the display of a *medical device*.

3.11
information supplied by the manufacturer
all information related to the identification and use of a *medical device* or *accessory*, 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: See Figure 1.

3.12
instructions for use
IFU
portion of the *accompanying information* that is essential for the safe and effective use of a *medical device* or *accessory* 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 standard, 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 communicated from *SaMD*.

Note 4 to entry: *Medical devices* or *accessories* that can be used safely without *instructions for use* are exempted from having *instructions for use* by some *authorities with jurisdiction.*

Note 5 to entry: See Figure 1.

3.13
label
<*medical device*, *accessory*> written, printed, or graphic information *marked* on the item itself, or 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: See Figure 1.

[SOURCE: IMDRF/GRRP WG/47:2018 [3], definition 3.21, modified –added note]

3.14
lay
lay person
<*user*, *responsible organization*> term referring to non-professional or professional without relevant specialized training

[SOURCE: IEC 60601-1-11:2015 [5], definition 3.3, modified –The reference to 'operator' has been replaced with '*user*'.]

3.15
lot
batch
defined amount of material or a number of *medical devices*, including finished product and *accessories*, that is manufactured in one *process* or a series of related *processes* and is homogenous

NOTE 1 to entry: A *batch* or *lot* is manufactured under essentially the same conditions and is intended to have uniform characteristics and quality within specified limits. A *batch* or *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* is normally associated with a unique statement of conformity to a defined quality specification.

3.16
lot number
batch code
batch number
lot code
production identifier containing a combination of letters or numbers associated with a single *batch* or *lot*

3.17
marking
information, in text or graphical format, durably affixed printed, etched (or equivalent) to a *medical device* or *accessory*

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, from *SaMD* may provide marking via a display or communication interface.

Note 3 to entry: For the purposes of this document, *marking* is different from 'direct marking' as described in unique device identification (UDI).

