SIST

SLOVENSKI STANDARD
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Nadomešča:
SIST EN 1041:2008+A1:2013

Medicinski pripomočki - Informacije, ki jih zagotovi proizvajalec (ISO 20417:2021, popravljena verzija 2021-12)

Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)

Medizinprodukte - Anforderungen an vom Hersteller bereitzustellende Informationen (ISO 20417:2021, korrigierte Fassung 2021-12)

Dispositifs médicaux - Informations à fournir par le fabricant (ISO 20417:2021, Version corrigée 2021-12)

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European foreword

This document (EN ISO 20417:2021) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with Technical Committee CEN/CLC/JTC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2021, and conflicting national standards shall be withdrawn at the latest by November 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 1041:2008+A1:2013.

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Endorsement notice

The text of ISO 20417:2021, Corrected version 2021-12 has been approved by CEN as EN ISO 20417:2021 without any modification.

INTERNATIONAL STANDARD

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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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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

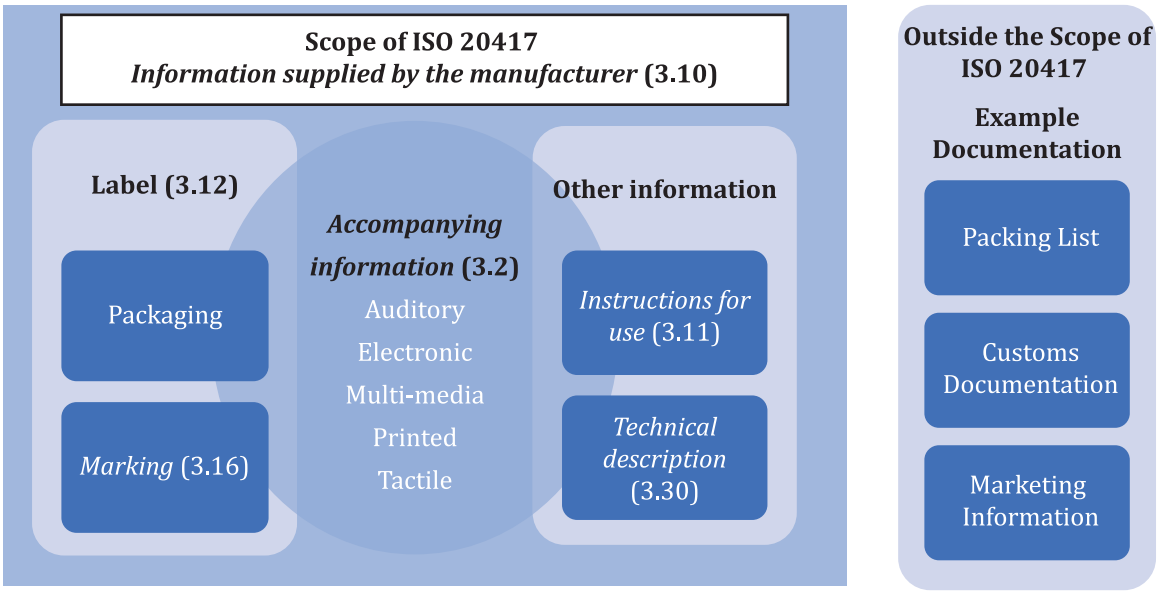
3.2
accompanying information
information accompanying or *marked* on a *medical device* or *accessory* (3.1) for the *user* or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the *medical device* or *accessory*, particularly regarding safe use

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.]