SLOVENSKI STANDARD
SIST EN ISO 20417:2026

01-junij-2026

Nadomešča:
SIST EN ISO 20417:2021

Medicinski pripomočki - Informacije, ki jih zagotovi proizvajalec (ISO 20417:2026)

Medical devices - Information to be supplied by the manufacturer (ISO 20417:2026)

Medizinprodukte - Anforderungen an vom Hersteller bereitzustellende Informationen (ISO 20417:2026)

Dispositifs médicaux - Informations à fournir par le fabricant (ISO 20417:2026)

Ta slovenski standard je istoveten z: **EN ISO 20417:2026**

ICS:

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

SIST EN ISO 20417:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20417

April 2026

ICS 11.040.01

Supersedes EN ISO 20417:2021

English version

Medical devices - Information to be supplied by the manufacturer (ISO 20417:2026)

Dispositifs médicaux - Informations à fournir par le fabricant (ISO 20417:2026)

Medizinprodukte - Anforderungen an vom Hersteller bereitzustellende Informationen (ISO 20417:2026)

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CEN-CENELEC Management Centre:
Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 20417:2026 E

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European foreword

This document (EN ISO 20417:2026) has been 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 Technical Committee CEN-CENELEC/ 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of an identical text or by endorsement, at the latest by October 2026, and conflicting national standards shall be withdrawn at the latest by October 2026.

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

This document supersedes EN ISO 20417:2021.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 20417:2026 has been approved by CEN-CENELEC as EN ISO 20417:2026 without any modification.

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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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

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.

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.

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/

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

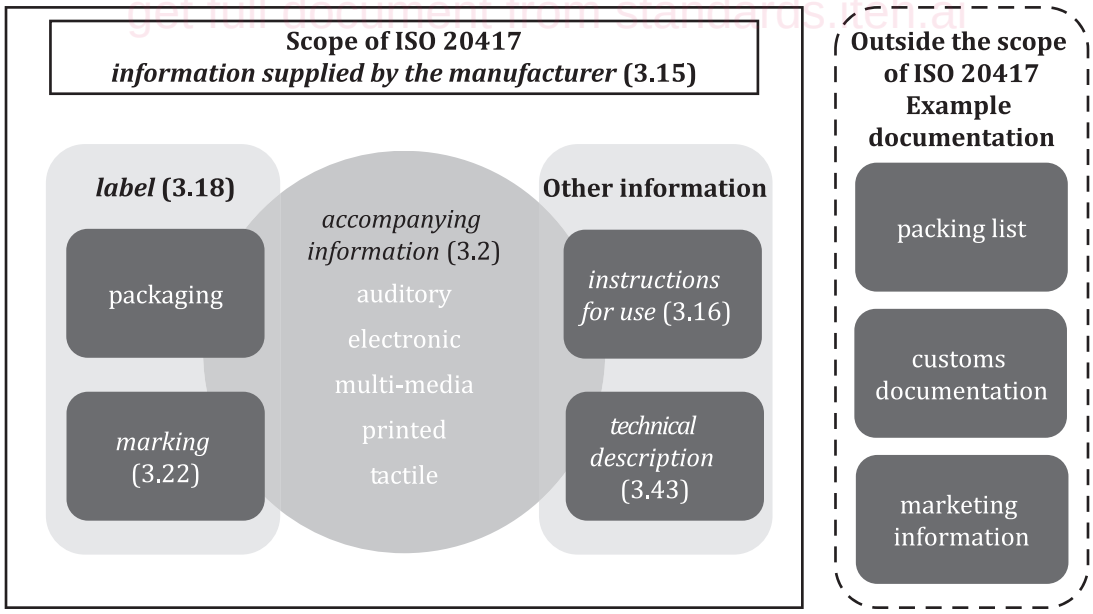
Note 1 to entry: The *accompanying information* is regarded as part of the *medical device* or *accessory*.

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*

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].