BSI Standards Publication

Medical devices — Information to be supplied by the manufacturer
National foreword


The UK participation in its preparation was entrusted to Technical Committee CH/210, Quality management and corresponding general aspects for medical devices.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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

Dispositifs médicaux - Informations à fournir par le fabricant (ISO 20417:2021)

Medizinprodukte - Anforderungen an allgemeine Informationen des Herstellers (ISO 20417:2021)

This European Standard was approved by CEN on 30 June 2020.

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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of an identical text or by endorsement, at the latest by November 2021, and conflicting national standards shall be withdrawn at the latest by November 2021.

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Endorsement notice

The text of ISO 20417:2021 has been approved by CEN as EN ISO 20417:2021 without any modification.
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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 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 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 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 (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 (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


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