



**NSAI**  
Standards

Irish Standard  
I.S. EN ISO 20417:2021

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

**I.S. EN ISO 20417:2021**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):*

*NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.*

*This document is based on:*

EN ISO 20417:2021

*Published:*

2021-05-05

*This document was published  
under the authority of the NSAI  
and comes into effect on:*

2021-05-28

ICS number:

11.040.01

NOTE: If blank see CEN/CENELEC cover page

NSAI  
1 Swift Square,  
Northwood, Santry  
Dublin 9

T +353 1 807 3800  
F +353 1 807 3838  
E standards@nsai.ie  
W NSAI.ie

Sales:  
T +353 1 857 6730  
F +353 1 857 6729  
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

## National Foreword

I.S. EN ISO 20417:2021 is the adopted Irish version of the European Document EN ISO 20417:2021, Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

**Compliance with this document does not of itself confer immunity from legal obligations.**

*In line with international standards practice the decimal point is shown as a comma (,) throughout this document.*

This page is intentionally left blank

EUROPEAN STANDARD

**EN ISO 20417**

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2021

ICS 11.040.01

Supersedes EN 1041:2008+A1:2013

English version

## 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.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of 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, Turkey and United Kingdom.



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

**EN ISO 20417:2021 (E)**

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>

## **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.

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, Turkey and the United Kingdom.

## **Endorsement notice**

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

This page is intentionally left blank



# INTERNATIONAL STANDARD

**ISO  
20417**

First edition  
2021-04

---

---

## **Medical devices — Information to be supplied by the manufacturer**

*Dispositifs médicaux — Informations à fournir par le fabricant*



Reference number  
ISO 20417:2021(E)

© ISO 2021

**ISO 20417:2021(E)**



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

Foreword .....	v
Introduction .....	vi
<b>1 Scope .....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>1</b>
<b>3 Terms and definitions .....</b>	<b>2</b>
<b>4 General considerations .....</b>	<b>9</b>
<b>5 Information elements to be established .....</b>	<b>10</b>
5.1 Units of measurement .....	10
5.2 Graphical information .....	10
5.3 Language and country identifiers .....	11
5.3.1 Language identifiers .....	11
5.3.2 Country identifiers .....	11
5.4 Dates .....	11
5.5 Full address .....	12
5.6 <b>Commercial product name</b> .....	12
5.7 <b>Model number</b> .....	12
5.8 <b>Catalogue number</b> .....	12
5.9 Production controls .....	12
5.10 Unique device identifier .....	13
5.11 Types of use/reuse .....	13
5.12 <b>Sterile</b> .....	13
<b>6 Requirements for accompanying information .....</b>	<b>13</b>
6.1 Requirements for information to be supplied on the <b>label</b> .....	13
6.1.1 Minimum requirements for the <b>label</b> .....	13
6.1.2 Identification of the <b>manufacturer</b> .....	14
6.1.3 Identification of the <b>medical device</b> or <b>accessory</b> .....	15
6.1.4 Other <b>label</b> requirements .....	17
6.1.5 Consult <b>instructions for use</b> .....	18
6.1.6 <b>Safety signs</b> .....	19
6.2 Identification requirements for detachable components of a <b>medical device</b> or <b>accessory</b> .....	20
6.3 Legibility of the <b>label</b> .....	20
6.4 Durability of <b>markings</b> .....	20
6.5 Information to be provided on the packaging .....	21
6.5.1 General information .....	21
6.5.2 Packaging for the <b>lay user</b> .....	22
6.5.3 Special conditions indicated on the packaging .....	23
6.6 Requirements for information in the <b>instructions for use</b> and <b>technical description</b> .....	24
6.6.1 General .....	24
6.6.2 Requirements for <b>instructions for use</b> .....	25
6.6.3 Additional requirements for the <b>instructions for use</b> for a <b>lay user</b> .....	30
6.6.4 Requirements for <b>technical description</b> .....	30
6.6.5 Requirements for <b>e-documentation</b> .....	33
<b>7 Other information that is required to be supplied with the medical device or accessory .....</b>	<b>33</b>
7.1 <b>Importer</b> .....	33
7.2 <b>Distributor</b> .....	33
7.3 Repackaging .....	34
7.4 Translation .....	34
7.5 Regulatory identification .....	35
<b>Annex A (informative) Particular guidance and rationale .....</b>	<b>36</b>
<b>Annex B (informative) Example test method for assessing clearly legible requirements .....</b>	<b>39</b>

**ISO 20417:2021(E)**

<b>Annex C (informative) Example test method for assessing durability .....</b>	<b>40</b>
<b>Annex D (informative) Cross reference between the document and the requirements considered .....</b>	<b>41</b>
<b>Annex E (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances .....</b>	<b>53</b>
<b>Annex F (informative) Reference to the <i>essential principles</i> .....</b>	<b>57</b>
<b>Annex G (informative) Reference to the general safety and performance requirements for <i>medical devices</i> .....</b>	<b>61</b>
<b>Annex H (informative) Reference to the general safety and performance requirements for <i>IVD medical devices</i> .....</b>	<b>65</b>
<b>Annex I (informative) Terminology — Alphabetized index of defined terms .....</b>	<b>69</b>
<b>Bibliography .....</b>	<b>71</b>

## 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](http://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](http://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](http://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](http://www.iso.org/members.html).

## ISO 20417:2021(E)

### 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<sup>[3]</sup> 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<sup>[4]</sup> 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<sup>[5]</sup> (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<sup>[6]</sup> (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:—<sup>1)</sup>, *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*

IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of the usability engineering process to medical devices*

1) Under preparation. Stage at the time of publication: ISO/FDIS 15223-1:2021.

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- Looking for additional Standards? Visit Intertek Inform Infostore
  - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-