



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)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Ta slovenski standard je istoveten z: prEN ISO 20417
ksIST prEN ISO 20417:2020
<https://standards.iteh.ai/catalog/standards/sist/56bc1636-1b93-4ab4-af44-05059825527d/ksist-pr-en-iso-20417-2020>

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
-----------	------------------------------	------------------------------

oSIST prEN ISO 20417:2019 **en**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[kSIST FprEN ISO 20417:2020](#)

<https://standards.iteh.ai/catalog/standards/sist/3bbcf63b-fb93-4ab4-af44-05059825527d/ksist-fpren-iso-20417-2020>

DRAFT INTERNATIONAL STANDARD

ISO/DIS 20417

ISO/TC 210

Secretariat: ANSI

Voting begins on:
2019-03-19Voting terminates on:
2019-06-11

Medical devices — Information to be provided by the manufacturer

Dispositifs médicaux — Informations à fournir par le fabricant

ICS: 11.040.01

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ksIST FprEN ISO 20417:2020](https://standards.iteh.ai/catalog/standards/sist/3bbcf63b-fb93-4ab4-af44-05059825527d/ksist-fpren-iso-20417-2020)<https://standards.iteh.ai/catalog/standards/sist/3bbcf63b-fb93-4ab4-af44-05059825527d/ksist-fpren-iso-20417-2020>

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING



Reference number
ISO/DIS 20417:2019(E)

© ISO 2019

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ksIST FprEN ISO 20417:2020](https://standards.iteh.ai/catalog/standards/sist/3bbcf63b-fb93-4ab4-af44-05059825527d/ksist-fpren-iso-20417-2020)

<https://standards.iteh.ai/catalog/standards/sist/3bbcf63b-fb93-4ab4-af44-05059825527d/ksist-fpren-iso-20417-2020>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

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
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ksIST FprEN ISO 20417:2020](https://standards.iteh.ai/catalog/standards/sist/3bbcf63b-fb93-4ab4-af44-05059825527d/ksist-fpren-iso-20417-2020)

<https://standards.iteh.ai/catalog/standards/sist/3bbcf63b-fb93-4ab4-af44-05059825527d/ksist-fpren-iso-20417-2020>

1	Contents	
2	Foreword	6
3	Introduction	7
4	1 Scope	8
5	2 Normative references	8
6	3 Terms and definitions	10
7	4 General <i>process</i> requirements	16
8	4.1 <i>Usability</i>	16
9	4.2 <i>Risk management</i>	17
10	5 General requirements	17
11	5.1 Units of measurement.....	17
12	5.2 Symbols and colours.....	17
13	5.3 Language and country identifiers	18
14	5.3.1 Language identifiers.....	18
15	5.3.2 Country identifiers.....	18
16	5.4 Dates.....	18
17	5.5 Full address	19
18	5.6 Authorized representative.....	19
19	6 <i>Medical device</i> identification	19
20	6.1 Commercial product name.....	19
21	6.2 <i>Model number</i>	19
22	6.3 <i>Catalogue number</i>	19
23	6.4 Software	20
24	6.5 Production identifier	20
25	6.6 Unique device identification	20
26	6.7 Types of reuse.....	20
27	6.8 <i>Sterile</i>	21
28	7 Requirements for packaging	21
29	7.1 General packaging.....	21
30	7.2 Packaging for <i>lay user</i>	23
31	7.3 Special conditions indicated on packaging.....	23
32	8 Requirements for information on the <i>label</i> and <i>marking</i>	24
33	8.1 Requirements for the <i>label</i>	24
34	8.1.1 Minimum requirements for the <i>label</i>	24
35	8.1.2 Identification of the <i>manufacturer</i>	25
36	8.1.3 Identification of the <i>medical device</i> or <i>accessory</i>	25
37	8.1.4 Additional <i>label</i> requirements	27
38	8.2 Consult <i>instructions for use</i>	29
39	8.3 <i>Safety signs</i>	29
40	8.4 Legibility of the <i>label</i> and <i>markings</i>	30
41	8.5 Durability of <i>markings</i>	30
42	9 Requirements for <i>accompanying documentation</i>	31
43	9.1 General	31
44	9.2 Health technology assessment (HTA).....	32
45	9.3 Requirements for <i>instructions for use</i>	32
46	9.3.1 General	32
47	9.3.2 Requirements for <i>E-documentation</i>	35
48	9.4 Requirements for <i>technical description</i>	36

iTech STANDARD PREVIEW
(standards.iteh.ai)

49	10	<i>Information supplied by the manufacturer</i>	38
50	10.1	<i>Importer</i>	38
51	10.2	<i>Distributor</i>	38
52		Annex A (informative) Particular guidance and rationale	39
53		Annex B (informative) Symbols and <i>safety signs</i> for marking	42
54		Annex C (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidance	48
55		Annex D (informative) Reference to the <i>essential principles</i>	53
56		Annex E (informative) Terminology — Alphabetized index of defined terms	58
57		Annex ZA (informative) Relationship between this European standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered	61
58			
59		Annex ZB (informative) Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered	64
60			
61		Annex ZC (informative) Relationship between this European standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered	67
62			
63		Annex ZD (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	70
64			
65		Annex ZE (informative) Relationship between this Document and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered	75
66			
67		Bibliography	82
68			

ISO/DIS 20417:2019(E)

69 **Foreword**

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

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

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

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

iTeh STANDARD PREVIEW

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

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

91 This is the first edition of ISO 20417.

92 ISO 20417 replaces EN 1041 [1] ¹.

¹ Numbers in square brackets refer to the Bibliography.

94 **Introduction**

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

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

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

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

106 In this document, the following print types are used:

107 — Requirements and definitions: roman type.

108 — Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative
109 text of tables is also in a smaller type.

110 — *Test specifications and terms defined in clause 3 of this document or as noted: italic type.*

111 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of
112 the conditions is true.

113 The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part
114 2. For the purposes of this document, the auxiliary verb:

115 — “shall” means that conformance with a requirement or a test is mandatory for conformance with this
116 document;

117 — “should” means that conformance with a requirement or a test is recommended but is not mandatory for
118 conformance with this document;

119 — “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement
120 or test);

121 — “can” is used to describe a possibility or capability; and

122 — “must” is used to express an external constraint.

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

124 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there
125 is guidance or rationale related to that item in Annex A.

126

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*

- 159 ISO 7010:2011, *Graphical symbols – Safety colours and safety signs – Registered safety signs*
 160 +Amendment 1:2012
 161 +Amendment 2:2012
 162 +Amendment 3:2012
 163 +Amendment 4:2013
 164 +Amendment 5:2014
 165 +Amendment 6:2014
 166 +Amendment 7:2016
 167 +Amendment 8:2017
 168 +Amendment 9:2018
- 169 ISO 8601:2004, *Data elements and interchange formats – Information interchange – Representation of dates and times*
 170
- 171 ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes*
- 172 ISO 14971:—² (ed 2), *Medical devices – Application of risk management to medical devices*
- 173 ISO 15223-1:2016, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied –Part 1: General requirements*
 174
- 175 ISO 15459-2, *Information technology – Automatic identification and data capture techniques – Unique identification – Part 2: Registration procedures*
 176
- 177 ISO 15459-4, *Information technology – Automatic identification and data capture techniques – Unique identification – Part 4: Individual products and product packages*
 178
- 179 ISO 15459-6, *Information technology – Automatic identification and data capture techniques – Unique identification – Part 6: Groupings*
 180 standards.iteh.ai/catalog/standards/sist/3bbcf63b-fb93-4ab4-af44-05059825527d/ksist-fpren-iso-20417-2020
- 181 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*
 182
 183
- 184 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*
 185
 186
- 187 ISO 22742:2010, *Packaging – Linear bar code and two-dimensional symbols for product packaging*
- 188 IEC 60417 (database), *Graphical symbols for use on equipment*
- 189 IEC 62366-1:2015+AMD1:—³, *Medical devices – Part 1: Application of the usability engineering process to medical devices*
 190
- 191 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.

ISO/DIS 20417:2019(E)

192 **3 Terms and definitions**

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

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

197 **3.1**198 ***accessory***

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

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

202 **3.2**203 ***accompanying information***

204 information accompanying or on a *medical device* or *accessory* and containing information for the *user* or those
205 accountable for the installation, use, maintenance, decommissioning and disposal of the *medical device* or
206 *accessory*, particularly regarding safe use

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

208 Note 2 to entry: The *accompanying information* can consist of the *instructions for use*, *technical description*, installation
209 manual, quick reference guide, etc.

210 Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory,
211 visual, or tactile materials and multiple media types.

(standards.iteh.ai)
https://standards.iteh.ai/catalog/standards/sist/3bbcf63b-fb93-4ab4-af44-05059825527d/ksist-fpren-iso-20417-2020

212 **3.3**213 ***catalogue number***

214 *product code*

215 letters, numbers or a combination of these assigned by a *manufacturer* for ordering one or more *medical devices*
216 or *accessories*

217 **3.4**218 **** clearly legible***

219 *easily legible*

220 capable of being read by a person with normal vision

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

222 **3.5**223 ***distributor***

224 natural or legal person in the supply chain who, on his own behalf, furthers the availability of a *medical device*
225 or *accessory* to the *user*

226 Note 1 to entry: More than one *distributor* may be involved in the supply chain.

227 Note 2 to entry: For the purposes of this document, persons in the supply chain involved in activities such as storage and
228 transport on behalf of the *manufacturer*, *importer* or *distributor*, are not *distributors*.

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

230 **3.7**

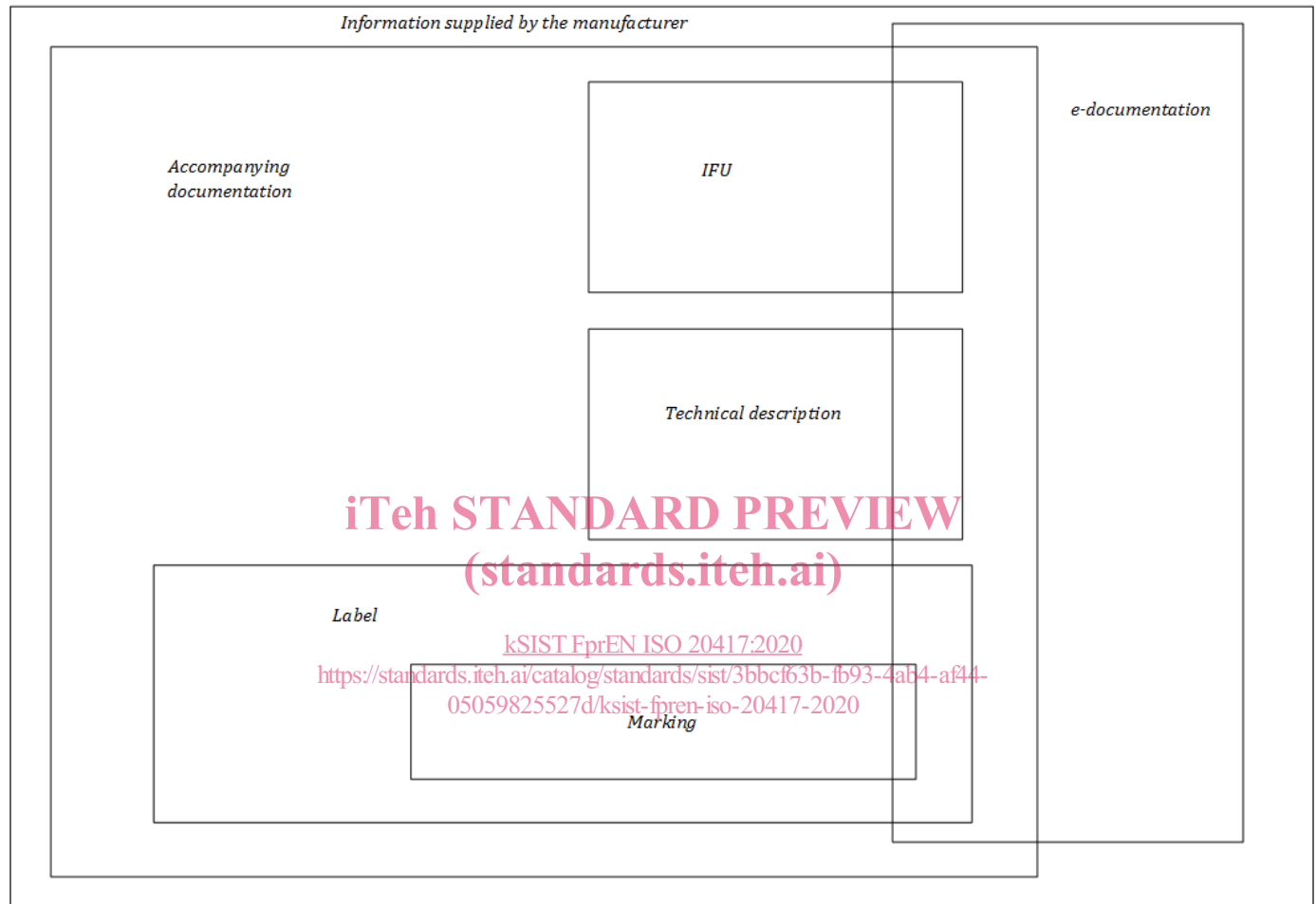
231 ***e-documentation***

232 ***electronic documentation***

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

234 EXAMPLE CD/DVD-ROM, Internet or other mode

235 Note 1 to entry: See Figure 1.



236
237 NOTE The *label* includes the packaging of the *medical device*.

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

239 **3.8**

240 ***expected lifetime***

241 ***expected service life***

242 time period specified by the *manufacturer* during which the *medical device* or *accessory* is expected to remain
243 safe for use

244 Note 1 to entry: The *expected lifetime* can be affected by the *stability*.

245 Note 2 to entry: Maintenance, repairs or upgrades (e.g. safety or cybersecurity modifications) can be necessary during the
246 *expected lifetime*.

247 [SOURCE: IEC 60601-1:2005+A1:2012, definition 3.28, modified –Added alternative term. The reference to
248 ‘me equipment or me system’ has been replaced with ‘*medical device*’, the parenthetical has been deleted and
249 the notes added.]

ISO/DIS 20417:2019(E)

250 **3.9**251 **importer**

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

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

256 **3.10**257 **information for safety**

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

259 EXAMPLE 1 Warnings, precautions or contraindications.

260 EXAMPLE 2 Instructions in the use of a *medical device* to prevent *use error* or avoid a *hazardous situation*.

261 EXAMPLE 3 Explanation of a safety feature of a *medical device*.

262 Note 1 to entry: *Information for safety* can be located on the display of a *medical device*.

263 **3.11**264 **information supplied by the manufacturer**

265 all information related to the identification and use of a *medical device* or *accessory*, in whatever form provided,
 266 intended to ensure the safe and effective use of the *medical device* or *accessory*

267 Note 1 to entry: For the purposes of this document, *e-documentation* is included in *information supplied by the*
 268 *manufacturer*.

269 Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from
 270 *information supplied by the manufacturer*. However, some authorities having jurisdiction can consider such supplemental
 271 information as *information supplied by the manufacturer*.

272 Note 3 to entry: See Figure 1.

273 **3.12**274 **instructions for use**275 **IFU**

276 portion of the *accompanying information* that is essential for the safe and effective use of a *medical device* or
 277 *accessory* directed to the *user* of the *medical device*

278 Note 1 to entry: For the purposes of this document, a *user* can be either a *lay user* or professional *user* with relevant
 279 specialized training.

280 Note 2 to entry: For the purposes of this standard, instructions for the professional *processing* between uses of a *medical*
 281 *device* or *accessory* can be included in the *instructions for use*.

282 Note 3 to entry: The *instructions for use*, or portions thereof, can be located on the display of a *medical device* or
 283 communicated from *SaMD*.

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

286 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).