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)

COPYRIGHT PROTECTED DOCUMENT

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

Published in Switzerland

Contents

Page

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.

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*

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.

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*.

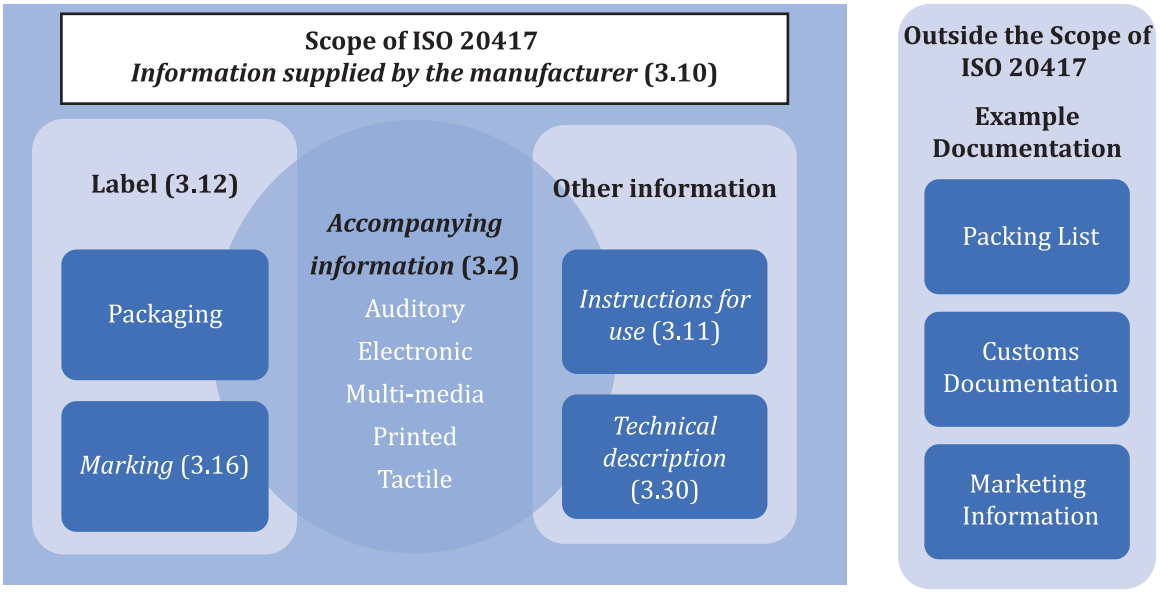
3.2
accompanying information
information accompanying or *marked* on a *medical device* or *accessory* (3.1) for the *user* or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the *medical device* or *accessory*, particularly regarding safe use

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*)

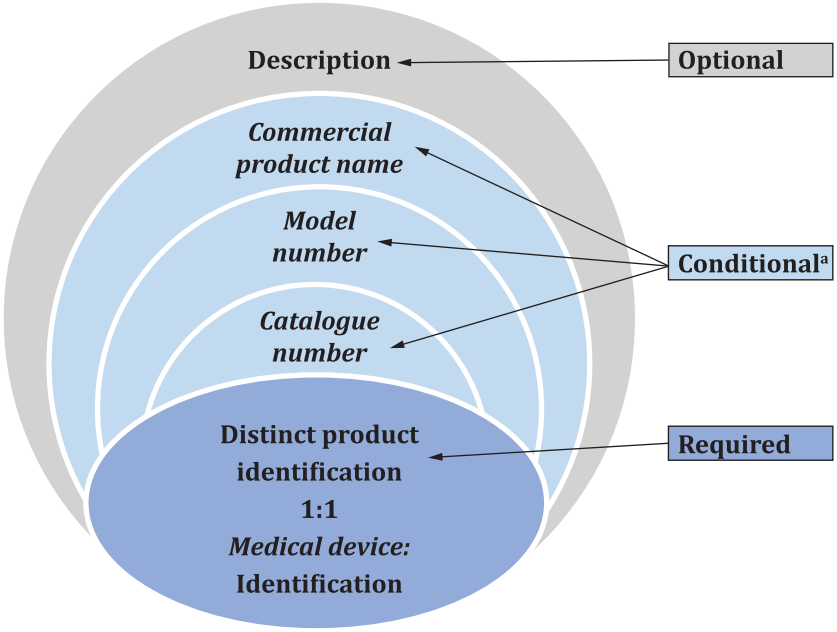
Note 1 to entry: A *catalogue number* shall consist of letters or numbers or a combination of these.

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.]



[a] At least one of these conditional distinct product identifiers is required.

Figure 2 — Relationship of terms used to describe distinct product identification

3.4
clearly legible
easily legible
capable of being read by a person with normal vision

Note 1 to entry: There is guidance or rationale for this definition contained in Clause A.2.

[SOURCE: IEC 60601-1:2005+AMD1:2012[2], 3.15, modified — Note 1 to entry added.]

3.5
distributor
natural or legal person, different from the *manufacturer* or *importer*, in the supply chain who, on their own behalf, furthers the availability of a *medical device* or *accessory* (3.1) to the *user*

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

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

Note 3 to entry: Distribution activities alone do not include repackaging or otherwise changing the container, wrapper, or *accompanying information* of the *medical device* or *medical device* package other than providing the identification of the *distributor*.

[SOURCE: ISO 13485:2016, 3.5[7], modified — added 'or *accessory*' and Note 3 to entry.]

3.6
e-documentation
electronic documentation
any form of electronically accessible *information supplied by the manufacturer* (3.10) related to a *medical device* or *accessory* (3.1)

EXAMPLE CD/DVD-ROM, USB stick, website.

Note 1 to entry: See Figure 1.

3.7
expected lifetime
expected service life
time period specified by the *manufacturer* during which the *medical device* or *accessory* (3.1) is expected to remain safe and effective for use

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

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

Note 3 to entry: Some *medical devices* have an absolute lifetime (e.g., 5 y), whereas other *medical devices* (e.g., software) have a relative lifetime (e.g., the time between two major releases).

Note 4 to entry: There is guidance or rationale for this definition contained in Clause A.2.

[SOURCE: IEC 60601-1:2005+AMD1:2012[2], 3.28, modified — added alternative term. The reference to 'me equipment or me system' has been replaced with '*medical device*', the parenthetical has been deleted and the notes added.]

3.8
importer
natural or legal person who imports a *medical device* or *accessory* (3.1) into a locale that was manufactured in another locale for the purposes of marketing

3.9
information for safety
information provided to the *user* or *responsible organization* as a *risk control* measure

EXAMPLE 1 Warnings, precautions or contraindications.

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

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

Note 1 to entry: *Information for safety* may be found in any or all types of *information supplied by the manufacturer*.

Note 2 to entry: *Information for safety* can be located on the display of a *medical device*.

3.10
information supplied by the manufacturer
information related to the identification and use of a *medical device* or *accessory* (3.1), in whatever form provided, intended to ensure the safe and effective use of the *medical device* or *accessory*

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

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

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the *medical device* and its *manufacturer*, and provide essential information about its safety, performance, and appropriate use to the *user* or other relevant persons.

Note 4 to entry: See Figure 1.

3.11
instructions for use
IFU
package insert
portion of the *accompanying information* that is essential for the safe and effective use of a *medical device* or *accessory* (3.1) directed to the *user* of the *medical device*

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

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

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

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

Note 5 to entry: See Figure 1.

3.12
label
<*medical device*, *accessory*> written, printed, or graphic information appearing on the item itself, 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: *Label* includes the *marking* on the *medical device* or *accessory*.

Note 3 to entry: For the purposes of this document, information indicated on a graphical user interface (GUI) is considered as appearing on the item.

Note 4 to entry: See Figure 1.

[SOURCE: IMDRF/GRRP WG/N52:2019[4], 3.17, modified –added notes and replaced 'unit' and 'devices' with 'item'.]

3.13
***l*ay**
lay person
individual who does not have formal education in a relevant field of healthcare or medical discipline and, if appropriate, relevant specialized training on the use of the specific *medical device*

3.14
lot
batch
defined amount of material or a number of *medical devices*, including finished product and *accessories* (3.1), that is manufactured in one *process* or a series of related *processes* and is intended to be homogenous

Note 1 to entry: A *lot* or *batch* is manufactured under essentially the same conditions and is intended to have uniform characteristics and quality within specified limits. A *lot* or *batch* 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* or *accessories* is normally associated with a unique statement of conformity to a defined quality specification.

3.15
lot number
batch code
batch number
lot code
production control containing a combination of letters or numbers associated with a single *lot* (3.14) or *batch* (3.14)

3.16
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *medical device* or *accessory* (3.1)

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, *marking* is different from 'direct marking' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct marking' is a type of *marking*.

Note 3 to entry: See Figure 1.

[SOURCE: ISO 18113-1:2009[8], 2.4, modified — replaced 'permanently' with 'durably', deleted notes and added Note 1 to entry and 'or *accessory*'.]

3.17
model number
model
letters, numbers or a combination of these assigned by a *manufacturer* to distinguish by function or type, a particular *medical device, accessory* (3.1) or *medical device family* from another

Note 1 to entry: See Figure 2.

3.18
multiple patient multiple use
<*medical device*, *accessory*> intended by the *manufacturer* to be reused on multiple *patients* for multiple uses

Note 1 to entry: A *multiple patient multiple use medical device or accessory* typically requires *processing* between *patients*.

Note 2 to entry: A *multiple patient multiple use medical device or accessory* may require *processing* between uses on a single *patient*.

3.19
pictogram
simplified pictorial representation, used to guide people and tell them how to achieve a certain goal

[SOURCE: ISO/IEC TR 20007:2014[9], 2.10]

3.20
processing
<preparation of *medical device*, *accessory*> activity to prepare a new or used *medical device* or *accessory* for its *intended use*

[SOURCE: ISO 11139:2018[10], 3.214, modified — added 'or, *accessory*'.]

3.21
safety sign
sign giving a general safety message, obtained by a combination of a colour and geometric shape and which, by the addition of a graphical *symbol*, gives a particular safety message

[SOURCE: ISO 7010:2019[11], 3.3]

3.22
serial number
production control containing a combination of letters or numbers, selected by the *manufacturer*, intended for quality control and identification purposes to uniquely distinguish an individual *medical device* from other *medical devices* with the same *catalogue number* or *model number*

[SOURCE: ISO 14708-2:2012[12], 3.20, modified — added 'production control containing a', replaced 'and/or' with 'or' and 'to distinguish a device from other devices with the same model designation' with 'for quality control and identification purposes to distinguish an individual *medical device* from other *medical devices* with the same *catalogue number* or *model number*'.]

3.23
service personnel
individuals or entity accountable to the *responsible organization* that install, assemble, maintain or repair a *medical device* or *accessory* (3.1)

[SOURCE: IEC 60601-1:2005[2], 3.113, modified — The reference to 'me equipment, me systems or equipment' has been replaced by 'a *medical device* or *accessory*'.]

3.24
shelf-life
period of time until the expiry date during which a *medical device* or *accessory* (3.1) in its original packaging maintains its *stability* under the conditions specified in the *information supplied by the manufacturer*

[SOURCE: IMDRF/GRRP WG/N52:2019[4], 3.36, modified — replaced 'by the manufacturer' with 'in the *information supplied by the manufacturer*'.]

3.25
single patient multiple use
<*medical device*, *accessory*> intended by the *manufacturer* to be reused on an individual *patient* for multiple uses

Note 1 to entry: A *single patient multiple use medical device* or *accessory* may require *processing* between uses.

Note 2 to entry: For an implantable *medical device*, the duration of a *single use* is from implanting to explanting the *medical device.*

3.26
single use
do not re-use
use only once
<*medical device*, *accessory*> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

Note 1 to entry: A *single use medical device* or *accessory* is not intended by its *manufacturer* to be further *processed* and used again.

3.27
stability
<*medical device*, *accessory*> ability to maintain safety and performance characteristics within the specifications in *information supplied by the manufacturer* (3.10)

Note 1 to entry: *Stability* applies to:

— *medical devices* whose performance, physical, chemical or functional properties can be altered or compromised over a stated time interval;

— the period of time over which sterility is assured;

— IVD reagents, calibrators and controls, when stored, transported and used in accordance with conditions specified in the *information supplied by the manufacturer*

— reconstituted lyophilized materials, working solutions and material removed from sealed containers, when prepared, used and stored according to the *information supplied by the manufacturer*; and

— measuring instruments or measuring systems after calibration.

Note 2 to entry: *Stability* of an IVD reagent or measuring system is normally quantified with respect to time:

— in terms of the duration of a time interval over which a measured property changes by a stated amount; or

— in terms of the change of a property under specified conditions.

3.28
sterile
free from viable microorganisms

[SOURCE: ISO 11139:2018[10], 3.271]

3.29
symbol
graphical representation appearing on the *label* and/or associated documentation of a *medical device* that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

Note 1 to entry: The *symbol* can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters (with sufficient justification).

[SOURCE: ISO 15223-1:—, 3.20]

3.30
technical description
portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing*, transport or storage for the *expected lifetime* of a *medical device*

Note 1 to entry: The *technical description* may be included in the *instructions for use*.

Note 2 to entry: See Figure 1.

3.31
UDI carrier
unique device identification carrier
means to convey the UDI by using automatic identification and data capture (AIDC) and, if applicable, its human readable interpretation (HRI)

Note 1 to entry: *UDI carriers* can include 1D/linear bar code, 2D/Matrix bar code, RFID, etc.

[SOURCE: MDRF/UDI WG/N7:2013[13]]

4 General considerations

a) The *risk management process* of ISO 14971:2019 and the *usability engineering process* of IEC 62366-1:2015+AMD1:2020 should be used to determine the information, including *information for safety*, to be provided in the *information supplied by the manufacturer.*

NOTE *Medical device*-specific standards can require additional *information supplied by the manufacturer*.

b) Where this document specifies a specific edition of a normatively referenced document, the *manufacturer* may substitute a more current version provided the *manufacturer* can demonstrate that the *residual risk* that results from the substitution remains acceptable and is comparable to the *residual risk* that results from applying the normatively referenced document.

c) *Information supplied by the manufacturer* shall be in a language that is appropriate to the intended *user*.

NOTE 1 The choice of language of the *information supplied by the manufacturer* can be required by the *authority having jurisdiction*.

NOTE 2 More than one language can be required in some jurisdictions.

d) The *accompanying information* shall specify any:

1) special skills, special training and special knowledge required of the intended *user* or the *responsible organization* that are necessary to be able to achieve the *intended use* of the *medical device;* and

2) if applicable, restrictions on the *use environment* that the *medical device* is intended to be used.

e) The *information supplied by the manufacturer* shall be written and presented in terms that are readily understood by the intended *users*, taking into account their education, training and any special needs, as appropriate.

NOTE *Medical device*-specific standards can require additional *usability* requirements.

Check conformance by inspection of the information supplied by the manufacturer.

5 Information elements to be established

5.1 Units of measurement

a) Numeric indications of parameters in the *information supplied by the manufacturer* shall be expressed in:

1) international system of units (SI) as specified in ISO 80000-1;

2) any other units required by a relevant *group standard* or *product standard*; or

3) any other units established by clinical convention.

b) For application of SI units, their multiples and certain other units, ISO 80000-1 shall apply.

Check conformance by inspection of the information supplied by the manufacturer.

5.2 Graphical information

a) Any graphical information that is replacing text such as *pictograms, symbols*, *safety signs* and safety-related identification colours used in the *information supplied by the manufacturer* shall have the meaning explained in the *accompanying documentation*.

NOTE Other requirements can be specified by the *authority having jurisdiction*.

b) *Symbols* used in the *information supplied by the manufacturer* should be found in:

1) ISO 7000 (database);

2) ISO 7010;

3) ISO 15223-1;

4) IEC 60417 (database);

5) IEC/TR 60878:2015[25]; or

6) if applicable:

i) relevant *product standards*; or

ii) relevant *group standards*.

c) *Symbols* should be used in the *information supplied by the manufacturer*.

Check conformance by inspection of the information supplied by the manufacturer as well as the instructions for use or e-documentation.

5.3 Language and country identifiers

5.3.1 Language identifiers

In multilingual *information supplied by the manufacturer*, the language name used:

a) should be clearly linked to the language used; and

b) may be identified using:

1) the plain text name of the language; or

EXAMPLE 1 In an English section: 'English' or 'en' or 'eng'.

EXAMPLE 2 In a French section: 'Français' or 'f'r or 'fra'.

EXAMPLE 3 In a Russian section: 'Русский' or 'ru' or 'rus'.

2) the language codes given in

i) ISO 639-1[22],

ii) ISO 639-2[23], or

iii) ISO 639-3[24].

Check conformance by inspection of the information supplied by the manufacturer.

5.3.2 Country identifiers

Where contact details for multiple countries are provided in the *information supplied by the manufacturer*, the country shall be identified using:

a) the country codes given in ISO 3166-1; or

b) the plain text of the country name in a language of that country.

Check conformance by inspection of the information supplied by the manufacturer.

5.4 Dates

Any human-readable date, other than the text associated with the *UDI carrier*, in the *information supplied by the manufacturer* shall be expressed in accordance with ISO 8601-1 in the format:

NOTE Other requirements can be specified by the *authority having jurisdiction*.

a) YYYY-MM-DD;

b) YYYY-MM; or

c) YYYY;

Check conformance by inspection of the information supplied by the manufacturer.

5.5 Full address

a) Where this document refers to a full address, the address shall contain the following elements insofar as they are available in the address system of the locale where the relevant entity (*manufacturer, distributor, importer* or authorized representative) is physically located:

   1) street/road;

   2) number/house/floor;

   3) city;

   4) state/region;

   5) postal code; and

   6) country.

b) The information regarding street/road and number/house/floor may be omitted if a postal code (corporate postal code) is used that fully replaces the indication of street/road and number/house/floor and is not a post office (PO) box number.

Check conformance by inspection of the information supplied by the manufacturer.

5.6 *Commercial product name*

A *medical device* may be identified with a *commercial product name* specific to the *medical device* or the *manufacturer*. A *commercial product name* is used to assist in the identification of a *medical device.*

5.7 *Model number*

a) A *model number* may be used to represent a *medical device*, an *accessory* or a *medical device family* that have shared characteristics.

b) A *model number* may be associated with multiple *catalogue numbers*.

c) The *model number* may be identical to the *catalogue number*, when there is a single *catalogue number* represented by the *model number*.

5.8 *Catalogue number*

a) A *medical device* or *accessory,* or a combination of *medical devices* or *accessories,* may be identified with a *catalogue number*.

b) Each unique *catalogue number* shall be related to a single, defined product specification.

c) Multiple *catalogue numbers* may be associated with a single *model number*.

Check conformance by inspection of the information supplied by the manufacturer.

5.9 Production controls

a) A production control associated with a *medical device* shall be identified by at least one of the following:

   1) *lot number;*

   2) *serial number;*

3) for *medical devices* containing cell tissues, donor identification information;

4) year and month by which it is to safe to use; or

5) year and month of manufacture.

b) This information shall identify a controlled group of products associated with the production *process* for identification and traceability.

Check conformance by inspection of the information supplied by the manufacturer.

5.10 Unique device identifier

a) Where necessary, a *medical device* or *accessory* shall be assigned a unique device identifier.

NOTE This can be required by the *authority having jurisdiction*,

b) This identifier shall have a 1:1 relation to:

1) a single *catalogue number*;

2) a single *model number*; or

3) a single *commercial product name*.

Check conformance by inspection of the information supplied by the manufacturer.

5.11 Types of use/reuse

A unique use classification shall be assigned at the level of *model number* or *catalogue number* from one of the following:

a) *single use;*

b) *single patient multiple use*; and

c) *multiple patient multiple use*.

Check conformance by inspection of the information supplied by the manufacturer.

5.12 *Sterile*

a) A *medical device* or *accessory* that is *sterile* shall be identified as *sterile*.

b) A *sterile medical device* or *accessory* shall be identified with the method of sterilization.

c) *Medical devices* or *accessories* available *sterile* and non-*sterile* shall have different:

1) *model numbers*; or

2) *catalogue numbers*.

Check conformance by inspection of the information supplied by the manufacturer.

6 Requirements for *accompanying information*

6.1 Requirements for information to be supplied on the *label*

6.1.1 Minimum requirements for the *label*

a) The information required in 6.1 shall be provided as a *label.*

b) The information on the *label* shall be provided in a human-readable format.

c) The information required in 6.1 shall be provided as a *marking* unless:

1) the size of the *medical device* or *accessory* does not allow fixation of this information on the *medical device* or *accessory*;

2) the nature of the outer surfaces does not allow fixation of this information on the *medical device* or *accessory; or*

3) the omission of these *markings* does not adversely affect the *benefit/risk* balance according to ISO 14971:2019.

Check conformance by inspection of the label and, if appropriate, the marking or risk management file.

6.1.2 Identification of the *manufacturer*

a) The *label* of a *medical device* or *accessory* shall include the name or trade name and, unless otherwise included in the *IFU*, the full address of

1) the *manufacturer*; and

2) where necessary, if the *manufacturer* does not have an address within the locale, an authorized representative within the locale,

to which the *responsible organization* can refer.

NOTE Item 2) can be required by the *authority having jurisdiction*.

b) In locales where the *manufacturer* or their authorized representative is required to be registered, the address used shall be the same as the registered address.

c) *Symbol* ISO 7000-3082 or *symbol* 5.1.1 from ISO 15223-1:— may be used to identify the *manufacturer*.

d) *Symbol* 5.1.2 from ISO 15223-1:— may be used to identify the authorized representative.

1) When using *symbol* 5.1.2 from ISO 15223-1:—, the 'EC' may be replaced by the 2-letter or 3-letter country code given in ISO 3166-1.

2) The address of the authorized representative may be applied by someone other than *manufacturer*.

EXAMPLE A *label* applied by the authorized representative and not the *manufacturer*.

i) An additional *label* shall not obscure any information on the *label* provided by the *manufacturer.*

e) The *medical device* or *accessory* may be *labelled* with the country of manufacture using either:

1) a text string; or

EXAMPLE Made in CC (where CC is the country code from ISO 3166-1)

2) *symbol* IEC 60417-6049 or *symbol* 5.1.11 from ISO 15223-1:—.

Check conformance by inspection of the label.

6.1.3 Identification of the *medical device* or *accessory*

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) The *label* of a *medical device* or *accessory* shall include all of the following

1) the details necessary for the *user* to identify:

i) the *medical device* or *accessory*; and

ii) its use.

EXAMPLE 'Drug Eluting Stent' or 'Blood Glucose Meter' or 'Pulse Oximeter' or 'Infusion Pump'.

2) a distinctive identification.

i) If a *model number* is used, it shall be identified by:

I) a text string; or

EXAMPLE For an English *label*: 'Model number xyz123' or 'model xyz123'.

II) *symbol* IEC 60417-6050.

ii) The *catalogue number* shall be identified by:

I) a text string; or

EXAMPLE For an English *label*: 'Catalogue number xyz123'.

II) *symbol* ISO 7000-2493 or *symbol* 5.1.6 from ISO 15223-1:—.

iii) If a *commercial product name* is used, it shall be expressed as a text string.

b) The *medical device* or *accessory* shall be *labelled* with all of the following:

1) any special storage or handling conditions;

i) These special storage or handling conditions may be kept to a minimum.

ii) In this case, more detailed information should appear in the *instructions for use*.

2) any special operating instructions that need to be brought to the immediate attention of the *user*; and

i) These special operating instructions may be kept to a minimum.

ii) In this case, more detailed information should appear in the *instructions for use*.

3) any necessary warnings or precautions that need to be brought to the immediate attention of the *user*.

i) These warnings or precautions may be kept to a minimum, in which case, more detailed information should appear in the *instructions for use*.

c) If the *medical device* or *accessory*, other than *IVD medical devices*, contains known allergens as well as phthalates or other substances, in a concentration that is above 0,1 % weight by weight, that are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction shall be *labelled* as containing such substances.

1) The *symbol* ISO 7000-2725 or *symbol* 5.4.5 from ISO 15223-1:— may be used for latex.

2) The *symbol* EN 15986:2011 may be used for phthalates.

3) The *symbol* ISO 7000-3723 or *symbol* 5.4.10 from ISO 15223-1:— may be used for endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction substances.

4) The *symbol* ISO 7000-2725 may be used for other substances.

d) If applicable, the *medical device* or *accessory* shall be *labelled* with all the following:

1) an indication that electronic *instructions for use* are available, if some or all of the *instructions for use* are *e-documentation;*

i) Electronic *instructions for use* may be indicated by

I) a text string indicating electronic *instructions for use*; or

II) *symbol* ISO 7000-1641 or *symbol* 5.4.3 of ISO 15223-1:—

1. with an accompanying e-*IFU* indicator, or

2. with a web address;

ii) Where applicable, the *label* shall include a reference to the accessibility or availability of this *e-documentation.*

iii) Where applicable, the *label* shall include the website address where the correct *instructions for use* can be consulted.

2) if intended for *single use*,

i) a text string indicating 'do not reuse',

ii) a text string indicating 'single use only', or

iii) *symbol* ISO 7000-1051 or *symbol* 5.4.2 from ISO 15223-1:—;

3) if intended for *single patient multiple use*,

i) a text string indicating 'single patient multiple use', or

ii) *symbol* ISO 7000-3706 or *symbol* 5.4.12 from ISO 15223-1:—;

4) if reuse is limited, the limitation on reuse;

EXAMPLE The maximum number of allowable reuses or *processing* cycles.

5) as *sterile* and identify the method of sterilization;

i) *Sterile* and the method of sterilization may be identified by:

I) a text string; or

II) as appropriate, with *symbol*

1. ISO 7000-2500 or *symbol* 5.2.2 from ISO 15223-1:—,

2. ISO 7000-2501 or *symbol* 5.2.3 from ISO 15223-1:—,

3. ISO 7000-2502 or *symbol* 5.2.4 from ISO 15223-1:—,

4. ISO 7000-2503 or *symbol* 5.2.5 from ISO 15223-1:—, or

5. *symbol* 5.2.10 from ISO 15223-1:—.

6) as containing biological origin substances; and

i) The *symbol* of ISO 7000-3701 or *symbol* 5.4.6 from ISO 15223-1:— may be used for containing human blood or plasma derivatives.

ii) The *symbol* of ISO 7000-3699 or *symbol* 5.4.8 from ISO 15223-1:— may be used for containing biological material of animal origin.

iii) The *symbol* of ISO 7000-3700 or *symbol* 5.4.9 from ISO 15223-1:— may be used for containing biological material of human origin.

iv) The *label* should also include the quantity, proportion or strength of that substance if the substance will be in direct contact with the *patient*.

NOTE This can be required by the *authority having jurisdiction*.

7) as containing medicinal substances.

i) The *symbol* of ISO 7000-3702 or *symbol* 5.4.7 from ISO 15223-1:— may be used for containing medicinal substances.

ii) The *label* should also include the quantity, proportion or strength of that substance if the substance will be in direct contact with the *patient*.

NOTE This can be required by the authority having jurisdiction.

e) If containing nanotechnology materials, the *medical device* or *accessory* should be *labelled* with containing nanotechnology materials.

1) The *symbol* ISO 7000-3703 or *symbol* 5.4.11 from ISO 15223-1:— may be used for containing nanotechnology materials.

f) If the *label* includes *symbols* or safety-related colours, they shall be explained in the *label*.

Check conformance by inspection of the label.

6.1.4 Other *label* requirements

a) The *label* of a *medical device* or *accessory* shall include production controls, as applicable:

1) *lot number*;

i) The *lot number* may be identified by:

I) a text string; or

II) *symbol* ISO 7000-2492 or *symbol* 5.1.5 from ISO 15223-1:—.

2) *serial number*;

i) The *serial number* may be identified by:

I) a text string; or

II) *symbol* ISO 7000-2498 or *symbol* 5.1.7 from ISO 15223-1:—.

3) the year, month and day by which it is safe to use; or

i) The date by which it is safe to use may be identified by:

I) a text string; or

II) *symbol* ISO 7000-2607 or *symbol* 5.1.4 from ISO 15223-1:—.

4) the year, month and day of manufacture, for a *medical device* or *accessory* without a date by which it is safe to use.

i) The date of manufacture may be identified by:

I) a text string;

II) *symbol* ISO 7000-2497 or *symbol* 5.1.3 from ISO 15223-1:—; or

III) *symbol* ISO 7000-3082 or *symbol* 5.1.1 from ISO 15223-1:—.

ii) The date of manufacture may be included in the *lot number* or *serial number*.

b) The *label* of a *medical device* or *accessory* shall include a unique device identifier (UDI).

NOTE This can be required by the *authority having jurisdiction.*

1) If more than one machine readable AIDC is on the *label*, *symbol* 5.7.10 from ISO 15223-1:— shall be used to identify the *UDI carrier*.

2) *Single use medical devices* or *accessories* need not be *marked* with a *UDI carrier.*

c) If the *medical device* or *accessory* is *sterile,* the *label* of a *medical device* or *accessory* shall include the year, month and day:

1) by which it is safe to use; or

i) The date by which it is safe to use may be identified by:

I) a text string; or

II) *symbol* ISO 7000-2607 or *symbol* 5.1.4 from ISO 15223-1:—.

2) of manufacture, for a *medical device* or *accessory* without a date by which it is safe to use.

i) The date of manufacture may be identified by:

I) a text string;

II) *symbol* ISO 7000-2497 or *symbol* 5.1.3 from ISO 15223-1:—; or

III) *symbol* ISO 7000-3082 or *symbol* 5.1.1 from ISO 15223-1:—.

ii) The date of manufacture may be included in the *lot number* or *serial number*.

d) The *label* of a *medical device* or *accessory* may include unique version identifier of the *label*.

e) If the *medical device*, other than an *IVD medical device*, is for use by a single person and has been manufactured according to a written prescription or pattern (e.g., it is a personalized *medical device*), the *label* shall indicate that it is for use by a single person.

Check conformance by inspection of the label.

6.1.5 Consult *instructions for use*

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) When the manufacturer uses consulting the accompanying information as a primary risk control measure for a specific risk, (e.g., the instructions for use contain information for safety), the medical device or accessory shall be labelled with:

1) the mandatory action *safety sign* ISO 7010-M002; or

2) a text string to the effect that it is a mandatory action to read the *instructions for use*.

b) Otherwise, *symbol* ISO 7000-1641 or *symbol* 5.4.3 from ISO 15223-1:— may be used to advise the *user* to consult the *instructions for use*.

Check conformance by inspection of instructions for use and the *risk management file.*

6.1.6 *Safety signs*

a) For the purpose of this subclause, where a *safety sign* is used to convey a warning, prohibition or mandatory action that mitigates a *risk* that is not obvious to the *user,* it shall be a *safety sign* selected from ISO 7010.

b) If a *safety sign* with an established meaning is appropriately used, the use of the general warning *safety sign* ISO 7010-W001 is not required.

NOTE In this context, warning is used to mean "There is certain danger"; prohibition is used to mean "You must not…"; and mandatory action is used to mean "You must…".

c) Where a *safety sign* is not available to indicate a particular desired meaning, the meaning may be obtained by one of the following methods.

1) Constructing a *safety sign* according to ISO 3864-1:2011, Clause7.

2) Using the general warning *safety sign* ISO 7010-W001 placed together with a supplementary *symbol* or text.

i) The text associated with the general warning *safety sign* shall be an affirmative statement (i.e., a safety notice) describing the principal *risk(s)* foreseen (e.g., "Causes burns", "Risk of explosion").

3) Using the general prohibition *safety sign* ISO 7010-P001 placed together with a supplementary *symbol* or text.

i) The text associated with the general prohibition *safety sign* shall be a statement (i.e., a safety notice) describing what is prohibited (e.g., "Do not open", "Do not drop").

4) Using the general mandatory action *safety sign* ISO 7010-M001 placed together with a supplementary *symbol* or text.

i) The text associated with the general mandatory action *safety sign* shall be a command (i.e., a safety notice) describing required action (e.g., "Wear protective gloves", "Scrub before entering").

d) If there is insufficient space to place the affirmative statement together with the *safety sign* on the *medical device* or *accessory*, the affirmative statement may be placed in the *instructions for use*.

NOTE The colours for *safety signs* specified in ISO 7010 are specified in ISO 3864-1 and it is important to use the specified colour.

e) Additionally, a safety notice should include the appropriate precautions or include instructions on how to reduce the *risk* (e.g., "Do not use for . . . ", "Keep away from . . .").

f) *Safety signs*, including any supplementary *symbol* or text:

1) shall be explained in the *instructions for use; and*

2) if colour is not utilized in the *instructions for use*, the colour of the *safety sign* shall be described in the *instructions for use*.

g) When supplementary text is placed together with *safety signs*, the supplementary text shall be in a language that is appropriate to the intended *user*.

NOTE 1 The choice of language of the *information supplied by the manufacturer* can be required by the *authority having jurisdiction*.

NOTE 2 More than one language is required in some jurisdictions.

Check conformance by inspection of the label and, if appropriate, the marking and, where appropriate, the instructions for use.

6.2 Identification requirements for detachable components of a *medical device* or *accessory*

If misidentification can result in an unacceptable *risk*, detachable components of a *medical device* or *accessory* shall be *labelled* with all of the following:

a) the name or trademark of the *manufacturer*;

b) a distinctive identification; and

   1) If a *model number* is used, it shall be identified by:

      i) a text string; or

         EXAMPLE For an English *label*: 'Model number xyz123' or 'Model xyz123'.

      ii) *symbol* IEC 60417-6050.

   2) If a *catalogue number* is used, it shall be identified by:

      i) a text string; or

         EXAMPLE For an English *label*: 'Catalogue number xyz123'.

      ii) *symbol* ISO 7000-2493 or *symbol* 5.1.6 from ISO 15223-1:—.

   3) If a *commercial product name* is used, it shall be expressed as a text string.

c) a production identifier in accordance with 6.1.4 a).

Check conformance by inspection of the label.

6.3 Legibility of the *label*

a) The *label* and *markings* required in 6.1 shall be *clearly legible* when viewed from the intended position of the *user* performing the related function.

b) The test method of Annex B may be used.

Check conformance for clear legibility with the results from an appropriate test.

6.4 Durability of *markings*

a) The *markings* on the *medical device* or *accessory* required in 6.1 shall be sufficiently durable to remain *clearly legible, as applicable,* during the *medical device's* or *accessory's*:

   1) *expected lifetime*; or

   2) *shelf-life*.

b) The *markings* required in 6.1 shall

   1) remain *clearly legible* under reasonably foreseeable environmental and mechanical impacts associated with the use of the *medical device*; and

2) be removable only:

i) with an extra-corporeal object that can be used to secure or release a fastener; or

ii) by appreciable force.

c) In considering the durability of the *markings*, the effect of *normal use* shall be taken into account.

d) The test method of Annex C may be used.

Check conformance for durability with the results from an appropriate test.

6.5 Information to be provided on the packaging

6.5.1 General information

a) For the purposes of this document, packaging need not include shipping containers.

b) The packaging of a *medical device* or *accessory* shall allow the identification of all the following:

1) the name or trade name and address of the *manufacturer*;

2) if the *manufacturer* does not have an address within the locale, the name and address of an authorized representative within the locale;

NOTE 1 This can be required by the *authority having jurisdiction*.

3) where necessary, a unique device identifier (UDI) as specified in 5.10, of the *medical device* or *accessory;*

NOTE 2 This can be required by the *authority having jurisdiction*.

i) If more than one machine readable AIDC is on the *label*, *symbol* 5.7.10 from ISO 15223-1:— shall be used to identify the *UDI carrier*.

ii) *Single use medical devices* or accessories need not be marked with a UDI carrier.

4) production controls, as appropriate:

i) *lot number*,

I) The *lot number* may be identified by:

1. a text string; or

2. *symbol* ISO 7000-2492 or *symbol* 5.1.5 from ISO 15223-1:—.

ii) *serial number*,

I) The *serial number* may be identified by:

1. a text string; or

2. *symbol* ISO 7000-2498 or *symbol* 5.1.7 from ISO 15223-1:—.

iii) for *medical devices* containing cell tissues, donor identification information;

iv) the year, month and day by which it is safe to use; or

I) The date may be identified by:

1. a text string; or

2. *symbol* ISO 7000-2607 or *symbol* 5.1.4 from ISO 15223-1:—.

v) the year, month and day of manufacture;

I) The date may be identified by:

1. a text string;
2. *symbol* ISO 7000-2497 or *symbol* 5.1.3 from ISO 15223-1:—; or
3. *symbol* ISO 7000-3082 or *symbol* 5.1.1 from ISO 15223-1:—.

5) a distinctive identification;

i) If a *model number* is used, it shall be identified by:

I) a text string; or

EXAMPLE For English packaging: 'Model number xyz123' or 'model xyz123'.

II) *symbol* IEC 60417-6050 or *symbol* 5.1.10 from ISO 15223-1:—.

ii) If a *catalogue number* is used, it shall be identified by:

I) a text string; or

EXAMPLE For English packaging: 'Catalogue number xyz123'.

II) *symbol* ISO 7000-2493 or *symbol* 5.1.6 from ISO 15223-1:—.

iii) If a *commercial product name* is used, it shall be expressed as a text string.

6) if *medical device* or *accessory* is intended for *single use*,

i) 'do not reuse',

ii) 'single use only', or

iii) *symbol* ISO 7000-1051 or *symbol* 5.4.2 from ISO 15223-1:—; and

7) if *medical device* or *accessory* is intended for *single patient multiple use*,

i) 'single patient multiple use', or

ii) *symbol* ISO 7000-3706 or *symbol* 5.4.12 from ISO 15223-1:—.

c) Where relevant, the package shall allow the identification of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms that accurately reflect the contents of the package.

Check conformance by inspection of the packaging.

6.5.2 Packaging for the *lay user*

a) In addition to the requirements of 6.5.1, if the *medical device* or *accessory* is intended to be presented to the *lay user* for retail sales and is intended for use by a *lay user*, the sales packaging shall allow the identification of the information needed by the *lay user* including, as a minimum all of the following:

1) the 'statement of intended use' otherwise known as a summary of *use specification*, unless the purpose is obvious to the intended *lay user* (see IEC 62366-1:2015+AMD1:2020, 5.1);

2) the information needed to select the proper size, if applicable;

NOTE There is guidance or rationale for this list item contained in Clause A.2.

3) any special requirements for a battery-powered *medical device.*

4) any special storage requirements (e.g., temperature and humidity ranges);

5) any necessary contraindications, warnings or precautions that need to be brought to the immediate attention of the *user*; and

NOTE For additional information, see IMDRF/GRRP WG/N52[4], 5.2.16.

6) safe disposal information for the *medical device* or *accessory*, if appropriate.

b) This information shall be visible under expected conditions of sale.

Check conformance by inspection of the packaging.

6.5.3 Special conditions indicated on the packaging

a) If special handling measures have to be taken during transport or storage, the packaging shall allow the identification of these measures accordingly.

NOTE 1 Graphical *symbols* for handling and storage of packages can be found in ISO 780[14] and ISO 15223-1.

NOTE 2 Additional graphical *symbols* for packages can be found in ISO 7000.

1) These environmental conditions for transport and storage may be identified, as appropriate, with the following *symbols:*

i) ISO 7000-0533 or *symbol* 5.3.6 from ISO 15223-1:—;

ii) ISO 7000-0534 or *symbol* 5.3.5 from ISO 15223-1:—;

iii) ISO 7000-0624 or *symbol* 5.3.2 from ISO 15223-1:—;

iv) ISO 7000-0626 or *symbol* 5.3.4 from ISO 15223-1:—;

v) ISO 7000-0632 or *symbol* 5.3.7 from ISO 15223-1:—;

vi) ISO 7000-2620 or *symbol* 5.3.8 from ISO 15223-1:—; or

vii) ISO 7000-2621 or *symbol* 5.3.9 from ISO 15223-1:—.

b) Where premature unpacking of a *medical device* or its parts could result in an unacceptable *risk*, the packaging shall allow identification of a suitable *safety sign* (see 6.1.6).

EXAMPLE 1 Humidity-sensitive or temperature-sensitive *medical devices*.

EXAMPLE 2 *Medical devices* containing hazardous substances and materials.

c) The packaging of a *medical device* or *accessory* supplied *sterile* shall allow the identification of all of the following*:*

1) an indication that the *medical device* or *accessory* is *sterile*;

2) the method of sterilization;

i) The method of sterilization may be identified by:

I) a text string; or

II) as appropriate, with *symbol*

— ISO 7000-2500 or *symbol* 5.2.2 from ISO 15223-1:—,

— ISO 7000-2501 or *symbol* 5.2.3 from ISO 15223-1:—,

— ISO 7000-2502 or *symbol* 5.2.4 from ISO 15223-1:—,

— ISO 7000-2503 or *symbol* 5.2.5 from ISO 15223-1:—, or

— 5.2.10 from ISO 15223-1:—.

3) the year, month and day by which it is safe to use;

i) The date may be identified by:

I) a text string; or

II) *symbol* ISO 7000-2607 or *symbol* 5.1.4 from ISO 15223-1:—.

4) an indication permitting the *sterile* packaging to be recognized as such if, at the point of use, the packaging system to be opened consists of more than one packaging layer;

i) The packaging system can be identified, as appropriate, with the following *symbols*:

I) ISO 7000-3704 or *symbol* 5.2.12 from ISO 15223-1:—,

II) ISO 7000-3707 or *symbol* 5.2.11 from ISO 15223-1:—,

III) ISO 7000-3708 or *symbol* 5.2.13 from ISO 15223-1:—,

IV) ISO 7000-3709 or *symbol* 5.2.14 from ISO 15223-1:—.

NOTE 1 The indication permitting the *sterile* packaging to be recognized as such differentiates between packaging layers that are validated as a *sterile*-barrier system from packaging layers that support aseptic presentation or protect from dust. This is particularly important for double-entry *sterile*-barrier systems as *risk control* for unintended contamination of the *sterile* field.

NOTE 2 Additional information can be found in ISO 11607-1[15] regarding requirements for multiple-layer *sterile*-barrier systems and *sterile* fluid path *medical devices* or *accessories* as well as guidance on ways to differentiate a *sterile*-barrier system from protective packaging.

5) instructions to check the *instructions for use* for what to do if the *sterile* packaging is damaged or unintentionally opened before use; and

i) When the instructions are to not use the *medical device* or *accessory symbol* ISO 7000-2606 or *symbol* 5.2.8 from ISO 15223-1:— may be used.

6) an indication on the *sterile* packaging permitting the *sterile* packaging to be recognised as such.

d) Where providing all of the information required in 6.5.3 a) to 6.5.3 c) is not practicable due to the size of the packaging, the remaining information may be provided in the *accompanying information*.

Check conformance by inspection of the packaging.

6.6 Requirements for information in the *instructions for use* and *technical description*

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

6.6.1 General

a) Unless the *medical device* or *accessory* can be used safely and effectively without the *instructions for use* and the *technical description*, the *accompanying information* shall include:

1) the information specified for inclusion in the *instructions for use*; and

2) the information specified for inclusion in the *technical description*.

3) The justification for any omission shall be evaluated according to ISO 14971:2019.

b) The information specified for inclusion in the *technical description* may be included in the *instructions for use*.

c) The information shall identify the *medical device* or *accessory* by including, as applicable, all the following:

1) the name or trade name and full address of

i) the *manufacturer*, and

ii) if the *manufacturer* does not have an address within the locale, an authorized representative within the locale,

NOTE Item ii) can be required by the *authority having jurisdiction.*

to which the *responsible organization* can refer;

2) contact information of the *manufacturer* to obtain technical assistance;

EXAMPLE Telephone number, fax number, website or email address.

3) the identity of the *medical device* or *accessory*, including at least one of the following:

i) the *commercial product name*;

ii) the *medical device family* name;

iii) the *model number*; or

iv) *catalogue number*; and

4) a description of the *medical device*.

d) Some *medical devices* may include separate *accompanying information* for the professional *user* and the *lay user*.

1) In this circumstance, the information for the professional *user* and the *lay user* shall be consistent.

2) In this circumstance, the information for the *lay user* shall clearly state the version of the information for the professional *user* to which it relates.

e) The information shall be created and presented in terms that are readily understood by the intended *users*, taking into account their education, training and any special needs, as appropriate.

1) Where appropriate, the *accompanying information* should be supplemented with drawings and diagrams near the corresponding text.

Check conformance by inspection of the accompanying information.

6.6.2 Requirements for *instructions for use*

a) The *instructions for use* shall document all the following:

1) The general information of 6.6.1;

2) the use of the *medical device* or *accessory* as intended by the *manufacturer;*

3) contain all *information for safety* necessary to safely use the *medical device* or *accessory* in accordance with its specifications;

4) the 'statement of intended use' otherwise known as a summary of the *use specification* (see IEC 62366-1:2015+AMD1:2020, 5.1);

   i) The language of this statement may be simplified in *instructions for use* intended for *lay users* provided key messages remain.

5) the performance of the *medical device* claimed by the *manufacturer*;

6) an explanation of any *residual risk*, including any foreseeable adverse events or side effects associated with the use of the *medical device* or *accessory*;

   i) This shall include

      I) any information that should be conveyed to the *patient* in this regard, and

      II) that the *user* should convey this information to the *patient*.

   ii) *Residual risks* shall be communicated as:

      I) limitations;

      II) contraindications;

      III) precautions; or

      IV) warnings.

7) any known contraindication(s) to the use of the *medical device* or *accessory*;

   i) This shall include any information to be conveyed to the *patient* in this regard.

8) unique version identifier of the *instructions for use*, such as a date of issue or revision number;

9) if applicable, those parts of the *medical device* that cannot be safely serviced or maintained while in use with a *patient*;

10) if applicable, safe disposal information for the *medical device*, its *accessories* and the consumables used with it, if any, including where appropriate:

    i) infection or microbial *hazards*;

    EXAMPLE Explants, needles or surgical equipment contaminated with potentially infectious substances of human origin.

    ii) environmental *hazards*; and

    EXAMPLE Batteries or materials that emit potentially hazardous levels of radiation.

    iii) physical *hazards* (e.g., from sharps);

11) if applicable, the details of any preparatory treatment or handling of the *medical device* before it is ready for use necessary to ensure that the *medical device* will perform as intended; and

    EXAMPLE Sterilization, identification of other necessary equipment not provided with the *medical device*, final assembly, reconstitution, calibration.

12) the information contained in 6.1.2, 6.1.3 and 6.5.3.

    i) The use of non-specific temperature or humidity indications that are open to interpretation, or that can vary according to geographic location shall be avoided unless further qualification is included.

b) The *instructions for use* should contain only the information most likely to be useful to the *user* or *responsible organization*.

NOTE The *instructions for use* are intended for the *lay* or professional *user* and the *responsible organization* to safely and effectively use the *medical device* to achieve the *intended use*. Additional details can be contained in the *technical description*.

c) The *instructions for use* shall include the specifications the *user* requires to use the *medical device* appropriately.

EXAMPLE If the *medical device* has a measuring function, the degree of accuracy claimed.

d) The *instructions for use* shall include information needed to determine whether the *medical device* is ready to perform safely and as intended, together with, where relevant:

1) details of any preparatory treatment or handling of the *medical device* before it is ready for use or during its use (e.g., final assembly, calibration);

i) This shall include:

I) any necessary information regarding acceptance and performance testing; and

II) associated acceptance criteria.

2) details of the nature, and frequency, of preventative and regular maintenance, and of any *processing*;

NOTE See the ISO 17664 (series)[16] for additional information about information to be provided concerning *processing*.

3) identification of any consumable components and how to replace them;

4) information on any necessary calibration to ensure that the *medical device* operates properly and safely during the *expected lifetime*;

5) methods of controlling the *risks* encountered by *users* involved in installing, calibrating or servicing the *medical device;*

6) any recommended quality control *procedures* to be taken to verify that the *medical device* performs as intended, including the following as applicable:

i) the *procedure* for using the available controls;

ii) instructions recommending the frequency of use;

iii) the limitations of the quality control *procedure*, clearly delineated;

iv) how the *user* should interpret the quality control *procedure* results, including a description of whether test results can or cannot be accepted when a quality control *procedure* fails; and

v) the actions to be taken if there is a failure of any of the controls; and

7) any requirements for special facilities (e.g., *sterile* field or clean room environment), or special training, or particular qualifications of the *user* or third parties.

e) For *medical devices* intended for use together with other *medical devices* or general-purpose equipment, the *instructions for use* shall include:

1) information to identify such *medical devices* or equipment in sufficient detail, in order to obtain a safe combination; and

2) information on any known restrictions to combinations of *medical devices* and equipment.

f) Where necessary, the *instructions for use* shall include:

NOTE This can be required by the *authority having jurisdiction*.

1) a specification of the clinical *benefit* to be expected; and

2) a brief overview of safety and clinical performance information relevant to the *user* or *patient*.

g) If the *medical device* is supplied *sterile*, the *instructions for use* shall include instructions to be followed in the event of the *sterile* packaging being damaged or unintentionally opened before use.

h) If the *medical device* is supplied non-*sterile* with the intention that it is sterilized before use, the *instructions for use* shall include the appropriate *processing* instructions for sterilization.

i) For a *medical device* or *accessory* intended for reuse, the *instructions for use* shall:

1) include the necessary information for the *processing* between uses; and

2) identify when the *medical device* or *accessory* can no longer be reused (e.g., signs of material degradation or the maximum number of allowable reuses).

j) The *instructions for use* shall include information of any warnings, precautions, measures to be taken and limitations of use regarding the *medical device* or *accessory*.

1) This shall include any information to be conveyed to the *patient* in this regard.

2) This information should be determined during the *risk management process* as well as from other relevant *group standards* and *product standards*.

3) This information should cover, where appropriate:

i) warnings, precautions or measures to be taken in the event of malfunction of the *medical device* or changes in its performance that may affect safety;

ii) warnings, precautions or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic *procedures*, pressure, humidity, or temperature;

iii) warnings, precautions or measures to be taken in regards to the *risks* of interference posed by the reasonably foreseeable presence of the *medical device* during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g., electromagnetic interference emitted by the *medical device* affecting other equipment);

iv) precautions related to materials incorporated into the *medical device* that are endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction or could result in sensitisation or allergic reaction of the *patient* or *user*;

v) warnings or precautions related to potentially infectious material present in the *medical device;*

vi) warnings or precautions for a *medical device* administering medicinal or biological products, including information that indicates any limitations or incompatibility in the type of substances to be delivered;

vii) warnings, precautions or measures to be taken in regards to calibration and maintenance requirements that could result in inaccurate measurements, diagnostic results or therapeutic treatment or use; and

viii) warnings or precautions on hazardous or potentially hazardous radiation, including:

I) the nature of the emitted radiation,

II) the means of protecting the *users*, bystanders, or where appropriate, *patients*,

III) the ways of avoiding misuse, and

IV) the ways of appropriately reducing the *risks* inherent during transport, storage and installation where applicable.

k) The *instructions for use* shall instruct the *user* and the *patient* to report any serious incident that has occurred in relation to the *medical device* to the *manufacturer* and the *authority having jurisdiction* in their locale.

l) Where multiple *medical devices* are provided to a single *user* or location, the *manufacturer* may provide a single copy of the *instructions for use*.

1) In this circumstance, the *manufacturer* should provide further copies upon request or make the *instructions for use* available as *e-documentation*.

m) If the *medical device* incorporates or includes a medicinal or biological substance, the *instructions for use* shall identify that substance or material.

1) In this circumstance, the *instructions for use* should also include the quantity, proportion or strength of that substance if the substance will be in direct contact with the *patient*.

n) If any indicators (e.g., humidity, temperature, shock) are provided within the packaging, the *instructions for use* shall include information describing:

1) their purpose and interpretation; and

2) what steps to take based on the indicator results.

o) The *instructions for use* shall include any applicable instructions to be followed in the event of the packaging being:

1) damaged;

2) unintentionally opened before use; and

3) if the packaging is exposed to environmental conditions outside of those specified.

p) For *medical devices* or *accessories* with electronic displays, text on those displays intended for the *user*, shall be *clearly legible*.

q) The *instructions for use* may include the information required in the *technical description*.

r) If the *medical device*, other than an *IVD medical device*, administers medicinal or biological products, the *instructions for use* shall indicate any limitations or incompatibilities in the choice of substances to be delivered.

s) If the *medical device* emits hazardous, or potentially hazardous levels of radiation for medical purposes, the *instructions for use* shall include detailed information as to:

1) the nature of the emitted radiation;

2) the type of the emitted radiation;

3) ways of avoiding misuse and of appropriately reducing the *risks* inherent to transport, storage and installation; and

4) where appropriate,

i) the intensity of the emitted radiation,

ii) the distribution of the emitted radiation,

iii) the recommended dose of the emitted radiation, and

iv) means of protecting the *patient*, the *user*, or a third party from unintended radiation during use of the *medical device.*

Check conformance by inspection of the instructions for use and, where appropriate, evaluation of the electronic display.

6.6.3 Additional requirements for the *instructions for use* for a *lay user*

a) Where the *patient* is an intended *user*, the *instructions for use* shall identify, as applicable:

   1) that the *patient* is an intended *user*; or

   2) that the *medical device* is intended for self-testing..

      NOTE For a *medical device* where the *intended use* includes the *patient* partially or fully operating the *medical device*, the *patient* becomes a *user*.

b) Where the intended *user* is a *lay user*, the *instructions for use* shall identify, where applicable:

   1) clearly and concisely the circumstances when the *user* should consult with a healthcare professional;

   2) a warning against servicing and maintenance while the *medical device* is in use;

   3) which functions the *lay user* can safely use;

   4) which functions the *lay user* cannot safely use; and

   5) which maintenance the *lay user* can perform (e.g., changing batteries).

      NOTE For a *medical device* where the *lay user* is allowed to perform restricted maintenance, the *lay user* becomes *service personnel*.

c) Where the intended *user* is a *lay user*, the *instructions for use* shall be available in a format appropriate and accessible to the *lay user*.

d) Where the intended *user* is a *lay user*, the *instructions for use* shall allow the intended *lay user*:

   1) to understand and apply, in order to correctly interpret, the result provided by the *medical device*; or

      i) Where applicable, the *instructions for use* shall include pictorial representations of all possible results (including when a *medical device* has failed to provide a valid result) for *medical devices* that give a visual readout.

   2) to confirm that the *medical device* is operating or has operated as intended.

e) Where the intended *user* is a *lay user* and the intended *use environment* includes home use, the *instructions for use* may omit some of the recommended elements of 6.6.2, provided this does not affect safety or performance.

   1) The justification for any omission shall be evaluated according to ISO 14971:2019.

Check conformance by inspection of the instructions for use.

6.6.4 Requirements for *technical description*

a) The *technical description* shall include all of the following:

   1) if separate from the *instructions for use*:

      i) the general information of 6.6.1;

      ii) the information in 6.6.2 a) 2);

      iii) the information in 6.6.2 a) 3); and

iv) the information in 6.6.2 a) 4);

2) information regarding any:

i) acceptance and performance testing; and

ii) recurrent testing and maintenance, including details of the means, methods and recommended frequency;

3) all critical characteristics of the *medical device*, as well as range and precision of all the measured or displayed values or performances or an indication where they can be found; and

4) a unique version identifier such as a date of issue or revision number.

b) The *technical description* shall provide all data that is essential for safe use, transport and storage, maintenance or repair, and measures or conditions necessary for installing the *medical device* and preparing it for use.

c) For a *medical device* with a wireless or wired electronic interface, the *technical description* shall include at least all of the following, as appropriate:

1) the purpose of the electronic interface including any *medical devices*, equipment, interface standard/specification, or software (including the unique identifier of the software) with which it is meant to connect;

2) the intended *user* of the interface;

3) whether the connection is meant to control the operations of another *medical device* or *accessory*;

4) the communication format (protocol) including:

i) the specifications for the interface (e.g., physiological waveforms, probe type or types, accuracy, frequency of response, update rate, data rate, bandwidth);

ii) the necessary performance and functional requirements from the *medical device* related to the sending or receiving of data or control;

iii) interface relevant standards used (including revision or date); and

iv) if applicable, a list of services provided (i.e., application program interfaces or API's);

5) the necessary interface specifications;

EXAMPLE Security needs for integration; type of physical connection; requirements for integrity; performance and functional requirements like accuracy, frequency of response, update rate, data rate and quality of service or QoS (bandwidth, latency, jitter/wander, time synchronization).

6) the list of the data attributes being exchanged or a reference to the standard defining the data attributes;

7) a summary of the testing performed on the interface to verify interoperability claims and any activities suggested for the *responsible organization* to verify safe use;

i) In the case where testing was performed to an interface specification and *verified* with a representative *medical device*, the *manufacturer* should specify the representative *medical device* used.

8) any method used for time synchronization;

NOTE 1 There is guidance or rationale for this list item contained in Annex A.2.

9) a description of any fault tolerance behaviour, boundary condition testing, or fail safe for critical functions (e.g., delivering energy) that allows the *user* to understand how to use the interface correctly;

10) any known limitations (what the *user* should not do), contraindications, precautions and warnings;

11) the recommended connections:

    i) the equipment with which the interface is intended to be connected; or

    ii) that interface is meant to be connected to unspecified equipment;

12) any recommended settings or configurations for the electronic interface;

13) list options for training or necessary qualifications for IT personnel, if applicable;

14) where the electronic interface is intended to connect to an IT network:

    i) the required characteristics of the IT network;

    ii) the required configuration of the IT network;

    iii) the technical specifications of the IT network connection including security specifications;

    iv) the intended information flow between electronic interface, the IT network and other equipment on the IT network, and the intended routing through the IT network; and

    v) a list of any *hazardous situations* resulting from a failure of the IT network to provide the characteristics required to meet the purpose of the electronic interface connection to the IT network;

15) the instructions for specific *users* such as IT personnel on how to connect or install and how to disconnect or uninstall the *medical device*; and

16) where the electronic interface is intended to connect to an IT network, the instructions to the *responsible organization* that:

    i) connection of the electronic interface to an IT network that includes other equipment could result in previously unidentified *risks* to *patients*, *users* or third parties;

    ii) the *responsible organization* should identify, analyse, evaluate and control these *risks*;

    NOTE 2 IEC 80001-1[17] provides guidance for the *responsible organization* to address these *risks*.

    iii) subsequent changes to the IT network could introduce new *risks* and require additional analysis; and

    iv) changes to the IT network include:

        I) changes in the IT network configuration;

        II) connection of additional items to the IT network;

        III) disconnecting items from the IT network;

        IV) update of equipment connected to the IT network; and

        V) upgrade of equipment connected to the IT network.

d) The *technical description* should include a description of any alarm conditions and information on *medical device* problems that need to be diagnosed before the *user* can determine the correct intervention.

Check conformance by inspection of the technical description.

6.6.5 Requirements for *e-documentation*

a) If the *manufacturer* has a website, the *instructions for use* of a *medical device* or *accessory* should be available on that website.

b) When the *instructions for use* are available on a website, the *label* of a *medical device* or *accessory* may include a two-dimensional code (e.g., QR Code) as specified in ISO 22742:2010[18] that can direct the *user* to the web address.

c) *Accompanying information* may be provided by *e-documentation*.

d) If *some* or all of the *accompanying information* is provided as *e-documentation,* the *manufacturer* shall determine whether information also needs to be provided by other means such as printed material or as *markings* on the *medical device* or *accessory*.

EXAMPLE Information to cover emergency operation.

NOTE The *usability engineering process* is a method for developing the *risk control* measures for *hazards* and *hazardous situations* related to use.

e) Where *accompanying information* is provided on a medium other than paper, the *manufacturer* shall ensure the *user* has information on how to:

1) view the *accompanying information*;

2) access the correct version of the *accompanying information*; and

3) obtain a paper version of the *accompanying information*.

Check conformance by inspection and using the two-dimensional symbol to locate the instructions for use.

7 Other information that is required to be supplied with the *medical device* or *accessory*

7.1 *Importer*

a) Where necessary, the *label* of a *medical device* or *accessory* shall include the name or trade name and full address of the *importer* to which the *responsible organization* can refer.

NOTE This can be required by the *authority having jurisdiction*.

1) *Symbol* ISO 7000-3725 or *symbol* 5.1.8 from ISO 15223-1:— may be used to identify the *importer.*

2) The address of the *importer* may be applied by someone other than the *manufacturer*.

EXAMPLE A *label* applied by the *importer* and not the *manufacturer*.

i) An additional *label* shall not obscure any information on the *label* provided by the *manufacturer.*

b) In locales where the *importer* is required to be registered, the address used shall be the same as the registered address.

Check conformance by inspection of the label.

7.2 *Distributor*

a) Where necessary, the *label* of a *medical device* or *accessory* shall include the name or trade name and full address of the *distributor* to which the *responsible organization* can refer.

NOTE This can be required by the *authority having jurisdiction*.

1) *Symbol* ISO 7000-3724 or *symbol* 5.1.9 from ISO 15223-1:— may be used to identify the *distributor.*

2) The address of the *distributor* may be applied by someone other than the *manufacturer*.

EXAMPLE A *label* applied by the *distributor* and not the *manufacturer*.

i) An additional *label* shall not obscure any information on the *label* provided by the *manufacturer.*

b) In locales where this entity is required to be registered, the address used shall be the same as the registered address.

Check conformance by inspection of the label.

7.3 Repackaging

a) Where necessary, the *label* of a *medical device* or *accessory* shall include the name or trade name and full address of the entity, other than the *manufacturer*, who has modified the original *medical device* or *accessory* packaging.

NOTE This can be required by the *authority having jurisdiction*.

1) *Symbol* ISO 7000-3727 or *symbol* 5.7.9 from ISO 15223-1:— may be used to identify this entity.

2) The indication of repackaging and the address of this entity shall be applied by someone other than the *manufacturer*.

i) An additional *label* shall not obscure any information on the *label* provided by the *manufacturer.*

b) Where necessary, the address used shall be the same as the registered address.

NOTE This can be required by the *authority having jurisdiction*.

Check conformance by inspection of the label.

7.4 Translation

a) Where necessary, the *label* of a *medical device* or *accessory* shall include the name or trade name and full address of the entity, other than the *manufacturer*, who is responsible for translated *label* or *IFU* of the original *medical device* or *accessory*.

NOTE This can be required by the *authority having jurisdiction*.

1) *Symbol* ISO 7000-3728 or *symbol* 5.7.8 from ISO 15223-1:— may be used to identify this entity.

2) The indication of translation and address of this entity shall be applied by someone other than the *manufacturer*.

i) An additional *label* shall not obscure any information on the *label* provided by the *manufacturer.*

b) In locales where this entity is required to be registered, the address used shall be the same as the registered address.

Check conformance by inspection of the label.

7.5 Regulatory identification

a) Where necessary, the *information supplied by the manufacturer* of a *medical device* or *accessory* shall include, as appropriate:

NOTE This can be required by the authority having jurisdiction.

1) regulatory reference information;

2) conformity graphics; and

3) regulatory classification graphics.

b) This information may be applied by someone other than *manufacturer*.

c) An additional *label* shall not obscure any information on the *label* provided by the *manufacturer.*

Check conformance by inspection of the label.

Annex A
(informative)

Particular guidance and rationale

A.1 General guidance

This Annex provides rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

A.2 General

The numbering of the following rationales corresponds to the numbering of the clauses and subclauses in this document. The numbering is, therefore, not consecutive.

— **Clause 1 – Scope**

The aim of this document is to serve as a source of the common, generally applicable requirements, whilst allowing each specific *product standard* or *group standard* to focus on the unique requirements for a specific *medical device* or group of *medical devices*. This document is intended to act as a means to support opportunities where harmonization efforts could be enhanced through its application.

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 *Labeling 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 D);

— 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 E);

— 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).

Annex D provides a cross reference between the requirements of this document and the above supported requirements.

Although combination products (a *medical device* with either a drug or biologic) are not explicitly excluded from the scope of this document, they are not explicitly treated. This is because there is not international harmonization of requirements for combination products.

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, 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*.

— **3.5** – ***Clearly legible***

Vision or visual acuity can be tested by reading a Snellen eye chart at a distance of 6 m. Near vision can be tested using a Jaeger test card. By examining a large number of people, researchers have decided what a “normal” human being should be able to see at various distances. That is the description of normal vision.

— **3.8** – ***Expected lifetime***

It is up to the *manufacturer* to define the *expected lifetime* of their *medical device*. Since the *risk management process* requires the *manufacturer* to verify the effectiveness of all *risk control* measures, the *manufacturer* needs to assess the effectiveness of *risk control* measures for the entire *expected lifetime* (or there could be an unacceptable *risk*).

Further many *authorities having jurisdiction* have all sorts of activities that *manufacturers* are required to perform during the lifetime of their *medical device*. *Manufacturers* are required to continue to perform post-production surveillance and ensure that their *medical device* remains safe (e.g., by providing security updates during that *expected lifetime*). Typically, software *manufacturers* express the *expected lifetime* in relative terms. For example, Microsoft supports Windows 7 and Windows 10, but no longer Windows 2000 or XP. Software *manufacturers* tend to support one or 2 major releases and continue to send service updates and patches during that *expected lifetime*, but not longer.

— **6.1.3** – **Identification of the *medical device* or *accessory***

The identification schemes used by *manufacturers* can be very simple or can be complicated. This document uses a hierarchal structure of terms to cover the possibilities. That hierarchy is represented in the following example:

— Airbus = *manufacturer* and *commercial product name*;

— A380 = a *model* family of Airbus;

— A380-900 = a *model number* (a variant in the *model* family, A380); and

— A380-900 xxx = *catalogue number* for a specific A380-900 (with options: e.g., engine type, avionics package).

Not all types of identifiers are required for all *medical devices*.

— **6.1.5** – **Consult *instructions for use***

During the *risk management process* of a *medical device* or *accessory*, if the *manufacturer* determines that reading information within the *instructions for use* is a mandatory action necessary to control a specific *risk* to an acceptable level, then the *safety sign* ISO 7010-M002 notifies the *user* of that need. In other words, if the means for a *user* to avoid a specific and unacceptable *risk* is only reading (and understanding) the *instructions for use*, then the *safety sign* is required. If the *user* does not read (and understand) those *instructions for use*, the *risk control* is ineffective and there is an unacceptable *risk*.

The *safety sign* ISO 7010-M002 should not be used for indicating that it is a mandatory action to read the *IFU* for the disclosure of *residual risk*.

— **6.5.2 – Packaging for *lay user***

a) 2)

These requirements are in addition to the requirements in 6.5.1 for the packaging of all *medical devices* or *accessories*. Some *medical devices* or *accessories* come in sizes where selecting the correct size is important for the safe and effective use of the *medical device* or *accessory*. Examples include sphygmomanometer cuffs and crutches. The *lay user* needs this information on the sales packaging to ensure that they can select the appropriate *medical device* or *accessory* prior to purchasing.

— **6.6 – Requirements for information in the *instructions for use* and *technical description***

The purpose of the *IFU* and *technical description* is to promote the safe and effective use of the *medical device* or *accessory* during its *shelf-life* or *expected lifetime*.

— **6.6.4 – Requirements for *technical description***

b) 8)

To collect meaningful data from multiple *medical devices*, the time stamps associated with the data need to be synchronized. To accomplish this, *medical devices* with an electronic interface need a method to have their internal time clocks synchronized to the local time. This disclosure provides the *responsible organization* with the information to accomplish this task.

— **Annex B – Example test method for assessing *clearly legible***

c)

When evaluating the observer's visual acuity, it is not necessary to have the observer tested by an eye physician. Confirming that the observer has an appropriate visual acuity can be performed by anyone just prior to the evaluation by utilizing a Snellen chart for a distance check or a Jaeger test card for a normal reading distance check. These charts are readily, commercially available and should be thought of as test equipment for this test.

Annex B
(informative)

Example test method for assessing *clearly legible* requirements

The test method in this annex provides one means of demonstrating conformance to the *clearly legible* requirements of 6.3. Other means are possible.

Check conformance for clearly legible with the following test:

a) *The medical device or its part is positioned so that the viewpoint is the intended position of the user.*

b) *If the intended position of the user is not specified and the position is not obvious, the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of (1 ± 0,1) m or for medical devices intended to be held in the hand, at a distance (0,4 ± 0,1) m. The ambient illumination is the least favourable illumination level in the range of 100 lx to 1 500 lx.*

c) *The observer has a visual acuity, corrected if necessary, of:*

NOTE There is guidance or rationale for this list item contained in Clause A.2.

— *0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20); or*

— *is able to read N6 of the Jaeger test card;*

as appropriate, in normal room lighting conditions, (500 ± 250) lx.

d) *The observer correctly reads the label or marking from the viewpoint. If the observer is in doubt, repeat with 3 additional observers. If all 3 additional observers confirm the legibility, consider the test as passing.*

Annex C
(informative)

Example test method for assessing durability

The test method in this annex provides one means of demonstrating conformance to the durability requirements of 6.4. Other means are possible.

Check conformance for durability by inspection and with the following test:

a) *For medical devices or accessories that are not single use, perform the number of processing cycles determined by the expected lifetime in accordance with the methods indicated in the instructions for use.*

b) *Rub the markings on the medical device or accessory by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96 % and then for 15 s with a cloth rag soaked with isopropyl alcohol.*

c) *Confirm that the markings remain clearly legible.*

Annex D
(informative)

Cross reference between the document and the requirements considered

Table D.1 provides a cross reference between the requirements of this document and the requirements of the considered references. The Directives 90/385/EEC, 93/42/EEC and 98/79/EC are included in this table to show the differences between these Directives and the new *medical device* regulations (EU) 2017/745 and (EU) 2017/746 to assist *manufacturers* in the transition of legacy *medical devices* from the Directives to the Regulations.

Table D.1 — Correspondence between this document and the requirements considered

This document	IMDRF/ GRRPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
4 a)		5.1.1, 5.3.1, 5.3.4	14.6, 22.1, 23.1 (a), 23.1 (g)	4 (c), 5 (b), 20.2 (m),	13	13.1	B. 8.1
4 b)							
4 c) 1)		5.3.4					
4 c) 2)		5.1.1, 5.3.1, 5.3.4	22.1				
4 d) 1)		5.1.1		13.7, 19.1			
4 d) 2)		5.1.1		13.7			
4 e)	5.1.5 b), 5.12.1	5.1.1, 9.3	5 (b), 14.6, 22.1, 23.1 (a)	5 (b), 19.1, 20.1 (a)		13.1	B. 8.1, B. 8.7 (t) first dash
5.1 a) 1)	5.9.1 b), 7.2.3		15.2	14.2			
5.1 a) 2)	5.9.1 b), 7.2.3		15.2	14.2			
5.1 a) 3)	5.9.1 b), 7.2.3		15.2	14.2			
5.1 b)			15.2	14.2			
5.2 a)		5.1.4,	23.1 (h)	20.1 (h)		13.2	B. 8.2
5.2 b) 1)		5.1.4	23.1 (h)	20.1 (h)		13.2	B. 8.2
5.2 b) 2)		5.1.4	23.1 (h)	20.1 (h)		13.2	B. 8.2
5.2 b) 3)		5.1.4	23.1 (h)	20.1 (h)		13.2	B. 8.2
5.2 b) 4)		5.1.4	23.1 (h)	20.1 (h)		13.2	B. 8.2
5.2 b) 5)		5.1.4	23.1 (h)	20.1 (h)		13.2	B. 8.2
5.2 b) 6) i)		5.1.4	23.1 (h)	20.1 (h)		13.2	B. 8.2
5.2 b) 6) ii)		5.1.4	23.1 (h)	20.1 (h)		13.2	B. 8.2
5.2 c)						13.2	B. 8.2
5.3.1 a)		5.1.3					
5.3.1 b) 1)		5.1.3					
5.3.1 b) 1) i)		5.1.3					
5.3.1 b) 1) ii)		5.1.3					
5.3.1 b) 1) iii)		5.1.3					
5.3.2 a)							
5.3.2 b)							
5.4 a)		5.2.14					
5.4 b)							
5.4 c)							

Table D.1 *(continued)*

This document	IMDRF/ GR-RPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
5.5 a) 1)		5.2.9, 5.2.10					
5.5 a) 2)		5.2.9, 5.2.10					
5.5 a) 3)		5.2.9, 5.2.10					
5.5 a) 4)		5.2.9, 5.2.10					
5.5 a) 5)		5.2.9, 5.2.10					
5.5 a) 6)		5.2.9, 5.2.10					
5.5 b)		5.2.9, 5.2.10					
5.6		4.1					
5.7 a)		4.2					
5.7 b)		4.2					
5.7 c)		4.2					
5.8 a)		4.2					
5.8 b)		4.2					
5.8 c)		4.2					
5.9 a) 1)							
5.9 a) 2)							
5.9 a) 3)							
5.9 a) 4)				20.2 (h)	14.1 ninth dash		
5.9 a) 5)							
5.9 b)							
5.10 a)		4.3	23.2 (h)	20.2 (g)	12		B. 8.4 (b)
5.10 b) 1)		4.3	23.2 (h)		12		
5.10 b) 2)		4.3	23.2 (h)		12		
5.10 b) 3)		4.3	23.2 (h)		12		
5.11 a)			23.2 (n)			13.3 (f)	
5.11 b)							
5.11 c)							
5.12 a)	5.4.7		11.8, 23.2 (l)	11.6, 20.2 (l)	14.1 second dash, 15 second dash	13.3 (c)	B. 8.4 (c)
5.12 b)			23.2 (l)	20.2 (l)	14.1 first dash, 15 second dash	13.3 (m)	
5.12 c) 1)	5.4.7		11.8	11.6		8.7	
5.12 c) 2)	5.4.7		11.8	11.6		8.7	
6.1.1 a)		5.1.1, 5.2.1	23.1 (b), 23.2 (a)	20.1 (b)		13.1	B. 8.1
6.1.1 b)		5.1.1, 5.2.6	23.1 (c)	20.1 (b), 20.1 (c)			
6.1.1 c) 1)		5.1.1, 5.2.1		20.1 (b)			
6.1.1 c) 2)		5.1.1, 5.2.1		20.1 (b)			
6.1.1 c) 3)							
6.1.2 a) 1)	5.10.1	5.2.9	23.1, 23.2 (a), 23.2 (c)	20.1, 20.2 (a), 20.2 (c)	14.2 first dash	13.1, 13.3 (a)	B. 8.1, B. 8.4 (a)
6.1.2 a) 2)		5.2.10	23.2 (d)	20.2 (d)		13.3 (a)	B. 8.4 (a)
6.1.2 b)							
6.1.2 c)			23.1 (h)	20.1 (h)			B. 8.4 (a)
6.1.2 d)			23.1 (h)	20.1 (h)			
6.1.2 d) 1)							
6.1.2 d) 2)		5.2.10					
6.1.2 d) 2) i)							

Table D.1 *(continued)*

This document	IMDRF/ GRRPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.1.2 e) 1)							
6.1.2 e) 2)			23.1 (h)	20.1 (h)			
6.1.3 a) 1) i)	5.10.1	5.2.5	23.1, 23.2 (b)	20.1, 20.2 (b)		13.3 (b)	B. 8.4 (b)
6.1.3 a) 1) ii)		5.2.5	23.1, 23.2 (b)	20.2 (b)		13.3 (b)	
6.1.3 a) 2) i) I)		5.2.5	23.1, 23.2 (b)	20.2 (b)		13.3 (b)	B. 8.4 (b)
6.1.3 a) 2) i) II)		5.2.5	23.1, 23.2 (h), 23.2 (b)	20.2 (b)		13.3 (b)	B. 8.4 (b)
6.1.3 a) 2) ii) I)		5.2.5, 5.2.8	23.1, 23.2 (b)	20.2 (b)		13.3 (b)	
6.1.3 a) 2) ii) II)		5.2.5, 5.2.8	23.1, 23.1 (h), 23.2 (b)	20.1 (h), 20.2 (b)		13.3 (b)	B. 8.4 (b)
6.1.3 a) 2) iii)		5.2.4, 5.2.5	23.1, 23.2 (b)	20.2 (b)		13.3 (b)	B. 8.4 (b)
6.1.3 b) 1)	5.10.1	5.1.1	23.2 (k)	20.2 (k), 20.4.1 (k)	14.2 tenth dash	13.1, 13.3 (i)	B. 8.1, B. 8.4 (h)
6.1.3 b) 1) i)	5.10.1	5.3.21	23.2 (k), 23.4 (a)			13.1	B. 8.1
6.1.3 b) 1) ii)	5.10.1	5.3.21	23.2 (k), 23.4 (a)			13.1	B. 8.1
6.1.3 b) 2)	5.10.1	5.1.1		20.2 (o)		13.1, 13.3 (j), 13.4	B. 8.1, B. 8.4 (i)
6.1.3 b) 2) i)	5.10.1			20.2 (o)		13.1	B. 8.1
6.1.3 b) 3)	5.10.1	5.1.1, 5.2.17	23.2 (m)	20.1, 20.2 (m)		13.1, 13.3 (k)	B. 8.1. B. 8.4 (j)
6.1.3 b) 3) i)	5.10.1	5.2.17	23.2 (m)	20.1		13.1	B. 8.1
6.1.3 c)	5.10.1		10.4.5, 23.2 (f),	20.1		7.5	
6.1.3 c) 1)			23.1 (h), 23.2 (f)	20.1 (h)			
6.1.3 c) 2)			23.1 (h), 23.2 (f)	20.1 (h)			
6.1.3 c) 3)			23.1 (h), 23.2 (f)	20.1 (h)			
6.1.3 c) 4)			23.1 (h), 23.2 (f)	20.1 (h)			
6.1.3 c) 5)			23.1 (h), 23.2 (f)	20.1 (h)			
6.1.3 d) 1) i) I)							
6.1.3 d) 1) i) II)			23.1 (h)	20.1 (h)			
6.1.3 d) 1) ii)							
6.1.3 d) 1) iii)		5.3.6					
6.1.3 d) 2) i)		5.2.18	23.2 (n)	20.2 (p)		13.3 (f)	
6.1.3 d) 2) ii)		5.2.18	23.2 (n)	20.2 (p)		13.3 (f)	
6.1.3 d) 2) iii)		5.2.18	23.1 (h), 23.2 (n)	20.1 (h), 20.2 (p),		13.3 (f)	
6.1.3 d) 3) i)		5.2.18					
6.1.3 d) 3) ii)		5.2.18	23.1 (h), 23.2 (n)	20.1 (h)			
6.1.3 d) 4)		5.2.18	23.2 (o)				
6.1.3 d) 5)		5.2.15	23.2 (l)	20.2 (l)	14.1 first dash, 14.1 second dash	13.3 (c), 13.3 (m)	B. 8.4 (c)
6.1.3 d) 5) i) I)		5.2.15					B. 8.4 (c)
6.1.3 d) 5) i) II) 1		5.2.15	11.8, 23.1 (h)	20.1 (h)			B. 8.4 (c)
6.1.3 d) 5) i) II) 2		5.2.15	11.8, 23.1 (h)	20.1 (h)			B. 8.4 (c)
6.1.3 d) 5) i) II) 3		5.2.15	11.8, 23.1 (h)	20.1 (h)			B. 8.4 (c)

Table D.1 *(continued)*

This document	IMDRF/ GRRPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.1.3 d) 5) i) II) 4		5.2.15	11.8, 23.1 (h)	20.1 (h)			B. 8.4 (c)
6.1.3 d) 5) i) II) 5		5.2.15	11.8, 23.1 (h)	20.1 (h)			B. 8.4 (c)
6.1.3 d) 6)		5.2.16	23.2 (e)				
6.1.3 d) 6) i)		5.2.16	23.1 (h), 23.2 (e)	20.1 (h)			
6.1.3 d) 6) ii)		5.2.16	23.1 (h), 23.2 (e)	20.1 (h)			
6.1.3 d) 6) iii)		5.2.16	23.1 (h), 23.2 (e)	20.1 (h)			
6.1.3 d) 6) iv)		5.2.16	23.2 (e)				
6.1.3 d) 7)		5.2.16	23.2 (e)				
6.1.3 d) 7) i)		5.2.16	23.1 (h), 23.2 (e)	20.1 (h)			
6.1.3 d) 7) ii)		5.2.16	23.2 (e)				
6.1.3 e)							
6.1.3 e) 1)			23.1 (h)	20.1 (h)			
6.1.3 f)			23.1 (h)				
6.1.4 a) 1)		5.2.13	23.2 (g)	20.2 (f)		13.3 (d), 13.5	B. 8.4 (d)
6.1.4 a) 1) i) l)		5.2.13	23.2 (g)	20.2 (f)		13.3 (d), 13.5	B. 8.4 (d)
6.1.4 a) 1) i) II)		5.2.13	23.1 (h), 23.2 (g)	20.1 (h), 20.2 (f)		13.3 (d), 13.5	B. 8.4 (d)
6.1.4 a) 2)		5.2.13	23.2 (g)	20.2 (f)		13.3 (d), 13.5	B. 8.4 (d)
6.1.4 a) 2) i) l)		5.2.13	23.2 (g)	20.2 (f)		13.3 (d), 13.5	B. 8.4 (d)
6.1.4 a) 2) i) II)		5.2.13	23.1 (h), 23.2 (g)	20.1 (h), 20.2 (f)		13.3 (d), 13.5	B. 8.4 (d)
6.1.4 a) 3)		5.2.14	23.2 (i)	20.2 (h)		13.3 (e)	B. 8.4 (e)
6.1.4 a) 3) i) l)		5.2.14	23.2 (i)	20.2 (h)			B. 8.4 (e)
6.1.4 a) 3) i) II)		5.2.14	23.1 (h), 23.2 (i)	20.1 (h), 20.2 (h)			B. 8.4 (e)
6.1.4 a) 4)		5.2.14	23.2 (j)	20.2 (i)		13.3 (l)	
6.1.4 a) 4) i)		5.2.14	23.2 (j)	20.2 (i)			
6.1.4 a) 4) i) l)		5.2.14	23.2 (j)	20.2 (i)			
6.1.4 a) 4) i) II)		5.2.14	23.1 (h), 23.2 (j)	20.1 (h), 20.2 (i)			
6.1.4 a) 4) i) III)		5.2.14	23.1 (h), 23.2 (j)	20.1 (h), 20.2 (i)			
6.1.4 a) 4) ii)		5.2.14	23.2 (j)			13.3 (l)	
6.1.4 b)		5.2.1	23.1, 23.2 (h)	20.2 (g)	12		B. 8.4(b)
6.1.4 b) 1)		5.2.1, 5.2.7	23.1, 23.1 (h), 23.2 (h)	20.1 (h), 20.2 (g),	12		B. 8.4 (b)
6.1.4 b) 2)		5.2.1					
6.1.4 c) 1)		5.2.14	23.2 (i), 23.3 (i)	20.3 (g)	14.1 ninth dash		B. 8.4 (e)
6.1.4 c) 1) i) l)		5.2.14	23.2 (i), 23.3 (i)	20.3 (g)			B. 8.4 (e)
6.1.4 c) 1) i) II)		5.2.14	23.1 (h), 23.2 (i) 23.3 (i)	20.1 (h), 20.3 (g)			B. 8.4 (e)
6.1.4 c) 2)		5.2.14	23.2 (j), 23.3 (h),	20.1 (h)			
6.1.4 c) 2) i) l)		5.2.14	23.1 (h), 23.2 (j), 23.3 (h)	20.1 (h)			
6.1.4 c) 2) i) II)		5.2.14	23.1 (h), 23.2 (j), 23.3 (h)	20.1 (h)			

Table D.1 *(continued)*

This document	IMDRF/ GRRPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.1.4 c) 2) i) III)		5.2.14	23.1 (h), 23.2 (j), 23.3 (h)	20.1 (h)			
6.1.4 c) 2) ii)		5.2.14		20.2 (i)			
6.1.4 d)		5.1.2					
6.1.4 e)		6.1.1	23.2 (p)				
6.1.5 a) 1)							
6.1.5 a) 2)							
6.1.5 b)			23.1 (h)	20.1 (h)			
6.1.6 a)	5.1.4	5.1.4				13.2	B. 8.2, B. 8.4 (j)
6.1.6 b)	5.1.4	5.1.4					
6.1.6 c) 1)	5.1.4	5.1.4				13.2	B. 8.2
6.1.6 c) 2)	5.1.4	5.1.4				13.2	B. 8.2, B. 8.4 (j)
6.1.6 c) 3)	5.1.4	5.1.4				13.2	B. 8.2, B. 8.4 (j)
6.1.6 c) 4)	5.1.4	5.1.4				13.2	B. 8.2,
6.1.6 d)	5.1.4						
6.1.6 e)	5.1.4					13.3 (k)	B. 8.4 (j)
6.1.6 f) 1)	5.1.4	5.2.12				13.2	B. 8.2
6.1.6 f) 2)	5.1.4	5.2.12				13.2	B. 8.2
6.1.6 g)	5.1.4						
6.2 a)				20.2 (a)	11		
6.2 b)					11	13.5	B. 8.6
6.2 b) 1) i)					11	13.5	B. 8.6
6.2 b) 1) ii)						13.5	B. 8.6
6.2 b) 2) i)					11	13.5	B. 8.6
6.2 b) 2) ii)			23.1 (h)	20.1 (h)		13.5	B. 8.6
6.2 b) 3)					11	13.5	B. 8.6
6.2 c)					11	13.3 (d), 13.5	B. 8.4 (d), B. 8.6
6.2 c) 1) i)					11	13.3 (d), 13.5	B. 8.4 (d), B. 8.6
6.2 c) 1) ii)			23.1 (h)	20.1 (h)		13.3 (d), 13.5	B. 8.4 (d), B. 8.6
6.3 a)		5.1.1, 5.2 (following 5.2.19)	23.1 (a)	20.1 (a), 20.1 (c)			
6.3 b)		5.2 (following 5.2.19)	23.1 (a)	20.1 (a), 20.1 (c)			
6.4 a) 1)	5.1.6	5.2 (following 5.2.19)		6, 7			
6.4 a) 2)	5.1.6	5.2 (following 5.2.19)		6, 7			
6.4 b) 1)	5.1.6	5.2 (following 5.2.19)		6, 7			
6.4 b) 2) i)	5.1.6	5.2 (following 5.2.19)		6, 7			
6.4 b) 2) ii)	5.1.6	5.2 (following 5.2.19)		6, 7			
6.4 c)	5.1.6			6, 7			
6.4 d)	5.1.6	5.2 (following 5.2.19)		6, 7			

Table D.1 *(continued)*

This document	IMDRF/ GR-RPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.5.1 a)							
6.5.1 b) 1)	5.10.1		23.2 (a), 23.3 (d)	20.1, 20.2 (a), 20.2 (b), 20.3 (d)	14.1 third dash, 14.2 first dash	13.1, 13.3 (a)	B. 8.1, B. 8.4 (a)
6.5.1 b) 2)			23.2 (d)				
6.5.1 b) 3)		5.2.1		20.1 (g), 20.2 (g)	12	13.3 (b)	B. 8.4 (b)
6.5.1 b) 3) i)			23.1 (h)	20.1 (h)		13.3 (b)	B. 8.4 (b)
6.5.1 b) 3) ii)							
6.5.1 b) 4) i)		5.2.13	23.2 (g)			13.3 (d), 13.5	B. 8.4 (d), B 8.6
6.5.1 b) 4) i) I) 1		5.2.13	23.2 (g)			13.3 (d)	B. 8.4 (d)
6.5.1 b) 4) i) I) 2		5.2.13	23.1 (h)	20.1 (h)		13.3 (d)	B. 8.4 (d)
6.5.1 b) 4) ii)		5.2.13	23.2 (g)			13.3 (d)	B. 8.4 (d)
6.5.1 b) 4) ii) I) 1		5.2.13	23.2 (g)			13.3 (d)	B. 8.4 (d)
6.5.1 b) 4) ii) I) 2		5.2.13	23.1 (h)	20.1 (h)		13.3 (b), 13.3 (d)	B. 8.4 (b), B. 8.4 (d)
6.5.1 b) 4) iii)			23.2 (e)				
6.5.1 b) 4) iv)			23.2 (i)	20.2 (h)	14.1 seventh dash, 14.2 ninth dash	13.3 (e)	B. 8.4 (e)
6.5.1 b) 4) iv) I) 1						13.3 (e)	B. 8.4 (e)
6.5.1 b) 4) iv) I) 2			23.1 (h)	20.1 (h)			B. 8.4 (e)
6.5.1 b) 4) v)			23.3 (h)	20.3 (f)			
6.5.1 b) 4) v) I) 1				20.3 (f)			
6.5.1 b) 4) v) I) 2			23.1 (h)	20.1 (h), 20.3 (f)			
6.5.1 b) 4) v) I) 3			23.1 (h)	20.1 (h), 20.3 (f)			
6.5.1 b) 5)	5.10.1			20.2 (b)		13.3 (b)	B. 8.4 (b)
6.5.1 b) 5) i) I)	5.10.1			20.2 (b)			
6.5.1 b) 5) i) II)	5.10.1		23.1 (h)	20.1 (h), 20.2 (b)			
6.5.1 b) 5) ii) I)	5.10.1			20.2 (b)			
6.5.1 b) 5) ii) II)	5.10.1		23.1 (h)	20.2 (b), 20.1 (h)			
6.5.1 b) 5) iii)	5.10.1			20.2 (b)			
6.5.1 b) 6) i)			23.2 (n)	20.2 (p)		13.3 (f)	
6.5.1 b) 6) ii)			23.2 (n)	20.2 (p)		13.3 (f)	
6.5.1 b) 6) iii)			23.1 (h)	20.1 (h)		13.3 (f)	
6.5.1 b) 7) i)							
6.5.1 b) 7) ii)			23.1 (h)	20.1 (h)			
6.5.1 c)		5.2.3		20.2 (j)			
6.5.2 a) 1)					14.2 third dash, 14.2 fourth dash		

Table D.1 *(continued)*

This document	IMDRF/ GRRPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.5.2 a) 2)							
6.5.2 a) 3)							
6.5.2 a) 4)			23.2 (k)		14.2 tenth dash	13.3 (i)	B. 8.4 (h)
6.5.2 a) 5			23.2 (m)			13.3 (k)	B. 8.4 (j)
6.5.2 a) 6)							
6.5.2 b)							
6.5.3 a)					14.2 tenth dash	13.3 (i)	B. 8.4 (h)
6.5.3 a) 1) i)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 a) 1) ii)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 a) 1) iii)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 a) 1) iv)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 a) 1) v)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 a) 1) vi)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 a) 1) vii)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 a) 1) viii)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 a) 1) ix)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 a) 1) x)			23.1 (h)	20.1 (h)			B. 8.4 (h)
6.5.3 b)		5.2.2					
6.5.3 c) 1)		5.2.15	11.8, 23.3 (b)	11.6, 20.3 (b)	14.1 second dash, 14.1 seventh dash, 14.2 seventh dash	13.3 (c)	B. 8.4 (c)
6.5.3 c) 2)		5.2.15	23.3 (c)	20.3 (c)	14.1 first dash		
6.5.3 c) 2) i) I)		5.2.15	23.3 (c)				
6.5.3 c) 2) i) II) 1		5.2.15	11.8, 23.1 (h), 23.3 (c)	20.1 (h)			
6.5.3 c) 2) i) II) 2		5.2.15	11.8, 23.1 (h), 23.3 (c)	20.1 (h)			
6.5.3 c) 2) i) II) 3		5.2.15	11.8, 23.1 (h), 23.3 (c)	20.1 (h)			
6.5.3 c) 2) i) II) 4		5.2.15	11.8, 23.1 (h), 23.3 (c)	20.1 (h)			
6.5.3 c) 2) i) II) 5		5.2.15	11.8, 23.1 (h), 23.3 (c)	20.1 (h)			
6.5.3 c) 3)			23.3 (i)		14.1 seventh dash, 14.2 ninth dash	13.3 (e)	B. 8.4 (e)
6.5.3 c) 3) i) I)			23.3 (i)			13.3 (e)	B. 8.4 (e)
6.5.3 c) 3) i) II)			23.1 (h), 23.3 (i)	20.1 (h)		13.3 (e)	B. 8.4 (e)
6.5.3 c) 4)			23.3 (a)	20.3 (a)	14.1 second dash, 14.1 seventh dash, 14.2 seventh dash		
6.5.3 c) 4) i)			23.1 (h)	20.1 (h)			
6.5.3 c) 5)		5.3.23, 5.3.24	23.3 (j)		15. eighth dash		
6.5.3 c) 5) i)			23.1 (h)	20.1 (h)			

Table D.1 *(continued)*

This document	IMDRF/ GR-RPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.5.3 c) 6)			23.3 (a)		14.1 second dash, 14.1 seventh dash, 14.2 seventh dash		
6.5.3 d)			23.3 (a)				
6.6.1 a) 1)		5.3.3	23.1 (d)	20.1 (d)		13.1	B. 8.1
6.6.1 a) 2)		5.3.3		20.1 (d)		13.1	B. 8.1
6.6.1 a) 3)		5.3.3		20.1 (d)			
6.6.1 b)							
6.6.1 c) 1) i)	5.10.1	5.3.9	23.4 (a)	20.1, 20.4.1 (ad)	15. second dash	13.1, 13.6 (a)	B. 8.1, B. 8.7 (a)
6.6.1 c) 1) ii)				20.1, 20.4.1 (ad)		13.6 (a)	B. 8.7 (a)
6.6.1 c) 2)		5.3.9		20.4.1 (ad)			
6.6.1 c) 3)	5.10.1		23.2 (a), 23.2 (b)	20.1		13.6 (a)	B. 8.7 (a)
6.6.1 c) 3) i)	5.10.1	5.3.7	23.2 (a)	20.1, 20.4.1 (a)		13.6 (a)	B. 8.7 (a)
6.6.1 c) 3) ii)	5.10.1			20.1		13.6 (a)	B. 8.7 (a)
6.6.1 c) 3) iii)	5.10.1			20.1, 20.4.1 (b)		13.6 (a)	B. 8.7 (a)
6.6.1 c) 3) iv)	5.10.1			20.1, 20.4.1 (b)		13.6 (a)	B. 8.7 (a)
6.6.1 c) 4)		5.3.8			15. second dash	13.6 (a)	B. 8.7 (a)
6.6.1 d)		5.3.1, 9.3		5 (b)		13.1	B. 8.1
6.6.1 d) 1)		9.3					
6.6.1 d) 2)		9.3					
6.6.1 e)	5.12.1	5.1.1, 5.3.1		5 (b), 19.1, 20.1 (a)	13	13.1	B. 8.1
6.6.1 e) 1)	5.12.1	5.3.1	23.1 (a)			13.1	B. 8.1
6.6.2 a) 1)		5.1.1				13.1	B. 8.1
6.6.2 a) 2)		5.1.1, 5.3.8	23.4 (b)		15. second dash	13.1	B. 8.1, B. 8.5
6.6.2 a) 3)	5.1.3 c), 5.10.1	5.1.1, 5.3.17	4 (c), 23.1	4 (c), 20.1, 20.2 (m)		13.1, 13.6 (a)	B. 8.1, B. 8.7 (a)
6.6.2 a) 4)		5.1.1, 5.3.10		20.4.1 (e)	15. second dash		
6.6.2 a) 4) i)		5.1.1, 9.4					
6.6.2 a) 5)	5.10.1	5.3.11	23.1				
6.6.2 a) 6)	5.1.4, 5.10.1	5.1.1, 5.1.5, 5.3.17	4 (c) last sentence, 23.1 (g), 23.4 (g)	4 (c), 20.1 (g)	15. third dash	13.1, 2 third dash,	B. 8.1, A. 2 third dash
6.6.2 a) 6) i) I)	5.1.4, 5.10.1	5.1.1, 5.1.5, 5.3.17	23.1 (g), 23.4 (g)				
6.6.2 a) 6) i) II)	5.1.4, 5.10.1	5.1.1, 5.1.5, 5.3.17	23.1 (g), 23.4 (b), 23.4 (g)				
6.6.2 a) 6) ii) I)	5.1.4, 5.10.1	5.1.1, 5.1.5, 5.3.17	4 (c), 23.1 (g), 23.4 (g)				
6.6.2 a) 6) ii) II)	5.1.4, 5.10.1	5.1.1, 5.1.5, 5.3.17	4 (c), 23.1 (g), 23.4 (g)		15 sentence after ninth dash		
6.6.2 a) 6) ii) III)	5.1.4, 5.10.1	5.1.1, 5.1.5, 5.3.17	4 (c), 23.1 (g), 23.4 (g)		15 sentence after ninth dash	13.6 (a)	B. 8.7 (a)
6.6.2 a) 6) ii) IV)	5.1.4, 5.10.1	5.1.1, 5.1.5, 5.3.17	4 (c), 23.1 (g), 23.4 (g)			13.6 (a)	B. 8.7 (a)
6.6.2 a) 7)	5.10.1	5.1.1	23.4 (b)		15 sentence after ninth dash		

Table D.1 *(continued)*

This document	IMDRF/ GRRPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.6.2 a) 7)i)	5.10.1	5.1.1	23.4 (b)		15 sentence after ninth dash		
6.6.2 a) 8)		5.1.2, 5.3.29	23.4 (y)	20.4.1 (ae)		13.6 (q)	B. 8.7 (u)
6.6.2 a) 9)	5.10.1						
6.6.2 a) 10)	5.5.8, 5.10.1	5.3.22	14.7, 23.4 (v)	13.6, 20.4.1 (ac)		13.6 (n)	B. 8.7 (n), B. 8.7 (s)
6.6.2 a) 10) i)	5.5.8, 5.10.1	5.3.22 a)	23.4 (v)	13.6, 20.4.1 (ac) (i)			B. 8.7 (s)
6.6.2 a) 10) ii)	5.5.8, 5.10.1	5.3.22 b)		13.6, 20.4.1 (ac) (ii)			
6.6.2 a) 10) iii)	5.5.8, 5.10.1	5.3.22 c)	23.4 (v)	13.6, 20.4.1 (ac) (iii)			
6.6.2 a) 11)	5.10.1	5.3.18	22.3, 23.4 (a), 23.4 (i)	19.3, 20.4.1 (r)	15 fifth dash	13.6 (a)	B. 8.7 (a), B. 8.7 (o)
6.6.2 a) 12)		5.1.1, 5.3.21		20.4.1 (k)			
6.6.2 a) 12) i)		5.1.1, 5.3.21					
6.6.2 b)	5.10.1	5.1.1					B. 8.7 (t) second dash
6.6.2 c)	5.9.1 a), 5.10.1	5.1.1, 5.3.12	15.1, 23.4 (b), 23.4 (h)		15 second dash, 15 fifth dash	13.6 (p)	B. 4.1
6.6.2 d)	5.10.1	5.1.1, 5.3.20	22.3, 23.4 (i), 23.4 (k)	20.4.1 (s)	15 second dash	13.1, 13.6 (d)	B. 8.1, B. 8.7 (n)
6.6.2 d) 1)	5.10.1	5.1.1, 5.2.2	22.3, 23.4 (e), 23.4 (k)	15.3, 19.3, 20.4.1 (r)		13.6 (d)	B 8.7 (n), B. 8.7 (o)
6.6.2 d) 1) i) I)	5.10.1		22.3, 23.4 (e), 23.4 (k)	15.3, 19.3		13.6 (d)	B. 8.7 (n)
6.6.2 d) 1) i) II)	5.10.1		22.3, 23.4 (e), 23.4 (k)	15.3, 19.3		13.6 (d)	B. 8.7 (n)
6.6.2 d) 2)	5.10.1	5.3.20 a), 5.3.20 b)	22.3, 23.4 (k)	15.3, 19.3, 20.4.1 (s)	15 fifth dash	13.6 (d)	B. 8.7 (n)
6.6.2 d) 3)		5.3.20 c)	22.3, 23.4 (k)	19.3, 20.4.1 (s)	15 fifth dash	13.6 (d)	
6.6.2 d) 4)	5.10.1	5.3.20 d)	22.3, 23.4 (k)	19.3, 20.4.1 (s)	15 fifth dash	13.6 (d)	B. 8.7 (n)
6.6.2 d) 5)	5.10.1	5.3.20 e)	22.3, 23.4 (k)	19.3, 20.4.1 (s)	15 fifth dash	13.6 (d)	B. 8.7 (n)
6.6.2 d) 6)	5.10.1	5.3.14	22.3	19.3, 20.4.1 (t)	15 fifth dash	13.6 (d)	B. 8.7 (n)
6.6.2 d) 6) i)	5.10.1	5.3.14 a)	22.3	19.3		13.6 (d)	B. 8.7 (n)
6.6.2 d) 6) ii)	5.10.1	5.3.14 b)	22.3	19.3		13.6 (d)	B. 8.7 (n)
6.6.2 d) 6) iii)	5.10.1	5.3.14 c)	22.3	19.3		13.6 (d)	B. 8.7 (n)
6.6.2 d) 6) iv)		5.3.14 d)	22.3	19.3		13.6 (d)	B. 8.7 (n)
6.6.2 d) 6) v)		5.3.14 e)	22.3	19.3		13.6 (d)	B. 8.7 (n)
6.6.2 d) 7)		5.1.1	22.3, 23.4 (j)	19.3, 20.4.1 (p)			B. 8.7 (o)
6.6.2 e) 1)	5.10.1	5.3.27	14.1, 23.4 (q)	13.1, 20.4.1 (j)		13.6 (c)	B. 8.7 (m)
6.6.2 e) 2)	5.5.1, 5.10.1	5.3.27	14.1, 23.4 (q)	13.1, 20.4.1 (j)		13.6 (c)	B. 8.7 (m)
6.6.2 f) 1)		5.1.6	23.4 (c)				
6.6.2 f) 2)	5.10.1	5.1.6	23.1, 23.4 (d), 23.4 (e)	20.4.1 (x)			
6.6.2 g)	5.10.1	5.3.23	23.4 (l)	20.4.1 (m)	15 eighth dash	13.6 (g)	B. 8.7 (p)
6.6.2 h)		5.3.25	23.4 (m)			13.6 (i)	B. 8.7 (o)
6.6.2 i) 1)		5.3.26	23.4 (n)	20.4.1 (n) (vi)		13.6 (h)	B. 8.7 (q)
6.6.2 i) 2)		5.3.26	23.4 (n)	20.4.1 (n) (vi)		13.6 (h)	B. 8.7 (q)
6.6.2 j)	5.10.1	5.1.1, 5.3.13	23.4 (s)	20.4.1 (n)		13.1, 13.6 (a)	B. 8.1, B. 8.7 (a)
6.6.2 j) 1)	5.10.1						

Table D.1 *(continued)*

This document	IMDRF/ GR-RPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.6.2 j) 2)	5.10.1						
6.6.2 j) 3) i)	5.10.1	5.3.13 a)	23.4 (s)	20.4.1 (n) (i)			
6.6.2 j) 3) ii)	5.10.1	5.3.13 b)	16.1 b), 23.4 (s)	20.4.1 (n) (ii)	15 twelfth dash	11.4.1, 13.6 (j), 13.6 (l)	B. 5.3, B. 8.7 (r)
6.6.2 j) 3) iii)	5.10.1	5.3.13 c)	23.4 (s)	20.4.1 (n) (iii)	15 seventh dash	13.6 (f)	
6.6.2 j) 3) iv)	5.10.1	5.3.13 d)	10.4.5, 23.4 (a), 23.4 (s)	20.4.1 (n) (iv)			
6.6.2 j) 3) v)	5.10.1	5.3.13 e)		20.4.1 (o)			B. 8.7 (s)
6.6.2 j) 3) vi)	5.10.1	5.3.15	23.4 (s) fourth dash		15 thirteenth dash	13.6 (m)	
6.6.2 j) 3) vii)	5.10.1						
6.6.2 j) 3) vii)	5.10.1			15.3			
6.6.2 j) 3) vii) I)	5.10.1					11.4.1, 13.6 (a)	B. 5.3, B. 8.7 (a)
6.6.2 j) 3) vii) II)	5.10.1					11.4.1	B. 5.3
6.6.2 j) 3) vii) III)	5.10.1					11.4.1	B. 5.3
6.6.2 j) 3) vii) IV)	5.10.1					11.4.1	B. 5.3
6.6.2 k)			23.4 (z)				
6.6.2 l)		5.3.2		20.1 (e)			
6.6.2 l) 1)		5.3.2	23.1 (e), 23.1 (f)				
6.6.2 m)		5.3.15	23.4 (a)				
6.6.2 m) 1)		5.3.15	23.4 (a)				
6.6.2 n) 1)		5.3.16					
6.6.2 n) 2)		5.3.16					
6.6.2 o) 1)		5.3.24			15 eighth dash	13.6 (g)	B. 8.7 (p)
6.6.2 o) 2)		5.3.24					
6.6.2 o) 3)		5.3.24					
6.6.2 p)		5.1.1		13.7	13		
6.6.2 q)							
6.6.2 r)		6.2.1	23.4 (s) 4th dash				
6.6.2 s) 1)	5.11.2, 5.10.1	5.3.28	23.4 (r)			13.6 (j)	B. 5.3
6.6.2 s) 2)	5.11.2, 5.10.1	5.3.28	23.4 (r)			13.6 (j)	
6.6.2 s) 3)							B. 5.3
6.6.2 s) 4)	5.11.2, 5.10.1	5.3.28	23.4 (r)			13.6 (j)	
6.6.2 s) 4) i)	5.11.2, 5.10.1	5.3.28	23.4 (r)			13.6 (j)	
6.6.2 s) 4) ii)	5.11.2, 5.10.1	5.3.28	23.4 (r)			13.6 (j)	
6.6.2 s) 4) iii)	5.11.2, 5.10.1	5.3.28	23.4 (r)				
6.6.2 s) 4) iv)	5.11.2, 5.10.1	5.3.28	23.4 (r)				
6.6.3 a) 1)				20.4.1 (e)			
6.6.3 a) 2)				20.2 (q), 20.4.1 (e)			
6.6.3 b) 1)		9.6	23.4 (w)				B. 8.7 (t) third dash
6.6.3 b) 2)							
6.6.3 b) 3)							
6.6.3 b) 4)							

Table D.1 *(continued)*

This document	IMDRF/ GRRPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.6.3 b) 5)							
6.6.3 c)		9.2		5 (b)			
6.6.3 d) 1)		9.1					
6.6.3 d) 1) i)		9.5					
6.6.3 d) 2)		9.1					
6.6.3 e)		9.4					
6.6.3 e) 1)		9.4					
6.6.4 a) 1) i)							
6.6.4 a) 1) ii)							
6.6.4 a) 1) iii)							
6.6.4 a) 1) iv)							
6.6.4 a) 2) i)				15.3			
6.6.4 a) 2) b)1)ii)							
6.6.4 a) 3)							
6.6.4 a) 4)		5.1.2					
6.6.4 b)							
6.6.4 c) 1)							
6.6.4 c) 2)							
6.6.4 c) 3)							
6.6.4 c) 4)							
6.6.4 c) 4) i)							
6.6.4 c) 4) ii)							
6.6.4 c) 4) iii)							
6.6.4 c) 4) iv)							
6.6.4 c) 5)							
6.6.4 c) 6)							
6.6.4 c) 7)							
6.6.4 c) 7) i)							
6.6.4 c) 8)							
6.6.4 c) 9)							
6.6.4 c) 10)							
6.6.4 c) 11) i)							
6.6.4 c) 11) b) 1) ii)							
6.6.4 c) 12)							
6.6.4 c) 13)							
6.6.4 c) 14) i)							
6.6.4 c) 14) ii)							
6.6.4 c) 14) iii)							
6.6.4 c) 14) iv)							
6.6.4 c) 14) v)							
6.6.4 c) 15)							
6.6.4 c) 16) i) l)							
6.6.4 c) 16) ii) l)							

Table D.1 *(continued)*

This document	IMDRF/ GRRPWG N47: 2018[3]	IMDRF/ GRRPWG N52: 2019[4]	(EU) 2017/745[5]	(EU) 2017/746[6]	90/385/EEC [OJ L 189][19]	93/42/EEC [OJ L 169][20]	98/79/EC [OJ L 331][21]
6.6.4 c) 16) iii) I)							
6.6.4 c) 16) iv) I)							
6.6.4 c) 16) iv) II)							
6.6.4 c) 16) iv) III)							
6.6.4 c) 16) iv) IV)							
6.6.4 c) 16) iv) V)							
6.6.4 d)							
6.6.5 a)		5.3.5	23.1 (f)				
6.6.5 b)		5.3.5	23.1 (f)				
6.6.5 c)		5.3.4	23.1 (f)				
6.6.5 d)			23.1 (f)	20.1 (a)			
6.6.5 e) 1)		5.3.6		20.1 (a), 20.2 (n)			
6.6.5 e) 2)		5.3.6		20.1 (a), 20.2 (n)			
6.6.5 e) 3)		5.3.6		20.1 (a)			
7.1 a)		5.2.11					
7.1 a) 1)		5.2.11	23.1 (h)	20.1 (h)			
7.1 a) 2)		5.2.11					
7.1 a) 2) i)		5.2.11					
7.1 b)							
7.2 a)		5.2.11					
7.2 a) 1)		5.2.11	23.1 (h)	20.1 (h)			
7.2 a) 2)		5.2.11					
7.2 a) 2) i)		5.2.11					
7.2 b)							
7.3 a)							
7.3 a) 1)			23.1 (h)	20.1 (h)			
7.3 a) 2)							
7.3 a) 2) i)							
7.3 b)							
7.4 a)							
7.4 a) 1)			23.1 (h)	20.1 (h)			
7.4 a) 2)							
7.4 a) 2) i)							
7.4 b)							
7.5 1)							
7.5 2)							
7.5 3)							
7.5 b)							
7.5 c)							

Annex E
(informative)

Reference to the IMDRF *essential principles* and labelling guidances

This document has been prepared to support the *essential principles* and labelling requirements of *information to be provided by the manufacturer* as part of a *medical device* according to the International Medical Device Regulators Forum (IMDRF). This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific *essential principles* of IMDRF/GRRP WG/N47:2018[3] and labelling principles IMDRF/GRRP WG/N52: 2019.[4] Other means are possible. Table E.1 maps the clauses and subclauses of this document with the *essential principles* of IMDRF/GRRP WG/ N47:2018. Table E.2 maps the clauses and subclauses of this document with the labelling principles of IMDRF/GRRP WG/N52:2019.

Table E.1 — Correspondence between this document and the *essential principles*

***Essential principle* of IMDRF/GRRP WG/N47:2018[3]**	**Corresponding clause(s)/ sub-clause(s) of this document**	**Qualifying remarks/Notes**
5.1.3 c)	6.6.2 a) 3)	The requirement for training is not addressed.
5.1.4	6.1.6, 6.6.2 a) 6)	
5.1.5 b)	4 e)	The requirement is only covered for the content of the *information supplied by the manufacturer.*
5.1.6	6.4	The requirement is only covered for the durability of the *marking* for the *expected lifetime.*
5.4.7	5.12 a), 5.12 c)	
5.5.1	6.6.2 e) 2)	Only the requirement to disclose restrictions in the *IFU* is covered.
5.5.8	6.6.2 a) 10)	Only the requirement to disclose safe disposal or recycling *procedures* and measures is covered.
5.9.1 a)	6.6.2 c)	
5.9.1 b)	5.1	
5.10.1	6.1.2 a) 1), 6.1.3 a) 1) i), 6.1.3 b), 6.1.3 c), 6.5.1 b) 1), 6.5.1 b) 5), 6.6.1 c) 1) i), 6.6.1 c) 3), 6.6.2	
5.11.2	6.6.2 s)	
5.12.1	4 e), 6.6.1 e)	Only the disclosure requirement is covered.
7.2.3	5.1	

Table E.2 — Correspondence between this document and the labelling principles

Labelling principles of IMDRF/GRRP WG/N52:2019[4]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
4.1	5.6	
4.2	5.7, 5.8	
4.3	5.10	
5.1.1	4 a), 4 c) 2), 4 d) 1), 4 d) 2), 4 e), 6.1.1 a), 6.1.1 b), 6.1.1 c) 1), 6.1.1 c) 2), 6.1.3 b) 1), 6.1.3 b) 2), 6.1.3 b) 3), 6.3 a), 6.6.1 e), 6.6.2 a) 1), 6.6.2 a) 2), 6.6.2 a) 3), 6.6.2 a) 4), 6.6.2 a) 4) i), 6.6.2 a) 6), 6.6.2 a) 7), 6.6.2 b), 6.6.2 c), 6.6.2 d) 1), 6.6.2 d) 7), 6.6.2 j)	
5.1.2	6.1.4 d), 6.6.2 a) 8), 6.6.4 a) 4)	
5.1.3	5.3.1	
5.1.4	5.2, 6.1.6 a), 6.1.6 c)	
5.1.5	6.6.2 a) 6)	The requirement only is covered when the *residual risks* are expressed as limitations, contraindications, precautions or warnings.
5.1.6	6.6.2 f)	
5.2 (following 5.2.19)	6.3, 6.4	
5.2.1	6.1.1 a), 6.1.1 c) 1), 6.1.1 c) 2), 6.1.4 b), 6.5.1 b) 3)	
5.2.2	6.5.3 b), 6.6.2 a) 12) i), 6.6.2 d) 1)	
5.2.3	6.5.1 c)	
5.2.4	6.1.3 a) 2) iii)	
5.2.5	6.1.3 a) 1)	
5.2.6	6.1.1 b)	
5.2.7	6.1.4 b) 1)	
5.2.8	6.1.3 a) 2) ii)	
5.2.9	5.5, 6.1.2 a) 1)	
5.2.10	5.5, 6.1.2 a) 2), 6.1.2 d) 2)	
5.2.11	7.1, 7.2	
5.2.12	6.1.6 f)	
5.2.13	6.1.4 a) 1), 6.1.4 a) 2), 6.5.1 b) 4) i), 6.5.1 b) 4) ii),	
5.2.14	5.4 a), 6.1.4 a) 3), 6.1.4 a) 4),	
5.2.15	6.1.3 d) 5), 6.5.3 c) 1), 6.5.3 c) 2)	
5.2.16	6.1.3 d) 6), 6.1.3 d) 7)	
5.2.17	6.1.3 b) 3) i)	
5.2.18	6.1.3 d) 2), 6.1.3 d) 3), 6.1.3 d) 4)	The requirement for *multiple patient multiple use* is not addressed.
5.2.19 (Last sentence)	6.4 a), 6.4 b), 6.4 d)	
5.3.1	4 a), 4 c) 2), 6.6.1 d), 6.6.1 e)	
5.3.2	6.6.2 l)	
5.3.3	6.6.1 a)	

Table E.2 *(continued)*

Labelling principles of IMDRF/GRRP WG/N52:2019[4]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.3.4	4 a), 6.6.5 c), 6.6.5 e)	The requirement for updates is not addressed.
5.3.5	6.6.5 a), 6.6.5 b)	
5.3.6	6.1.3 d) 1) iii), 6.6.5 e)	
5.3.7	6.6.1 c) 3) i)	
5.3.8	6.6.2 a) 2), 6.6.1 c) 4)	
5.3.9	6.6.1 c) 1) i), 6.6.1 c) 2)	
5.3.10	6.6.2 a) 4)	
5.3.11	6.6.2 a) 5)	
5.3.12	6.6.2 c)	
5.3.13	6.6.2 j)	
a)	6.6.2 j) 3) i)	
b)	6.6.2 j) 3) ii)	
c)	6.6.2 j) 3) iii)	
d)	6.6.2 j) 3) iv)	
e)	6.6.2 j) 3) v)	
5.3.14	6.6.2 d) 6)	
a)	6.6.2 d) 6) i)	
b)	6.6.2 d) 6) ii)	
c)	6.6.2 d) 6) iii)	
d)	6.6.2 d) 6) iv)	
e)	6.6.2 d) 6) v)	
5.3.15	6.6.2 j) 3) vi), 6.6.2 m)	
5.3.16	6.6.2 n)	
5.3.17	6.6.2 a) 3), 6.6.2 a) 6)	
5.3.18	6.6.2 a) 11)	
5.3.19	6.6.2 d) 7)	
5.3.20	6.6.2 d)	
a)	6.6.2 d) 2)	
b)	6.6.2 d) 2)	
c)	6.6.2 d) 3)	
d)	6.6.2 d) 4)	
e)	6.6.2 d) 5)	
5.3.21	6.1.3 b) 1), 6.6.2 a) 12)	
5.3.22	6.6.2 a) 10)	
a)	6.6.2 a) 10) i)	
b)	6.6.2 a) 10) ii)	
c)	6.6.2 a) 10) iii)	
5.3.23	6.5.3 c) 5), 6.6.2 g)	
5.3.24	6.5.3 c) 5), 6.6.2 o)	
5.3.25	6.6.2 h)	
5.3.26	6.6.2 i)	
5.3.27	6.6.2 e)	

Table E.2 *(continued)*

Labelling principles of IMDRF/GRRP WG/N52:2019[4]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.3.28	6.6.2 s)	
5.3.29	6.6.2 a) 8)	
6.1.1	6.1.4 e)	
6.2.1	6.6.2 r)	
9.1	6.6.3 d) 1), 6.6.3 d) 2)	
9.2	6.6.3 c)	
9.3	6.6.1 d)	
9.4	6.6.2 a) 4) i), 6.6.3 e)	
9.5	6.6.3 d) 1) i)	
9.6	6.6.3 b) 1)	

Annex F
(informative)

Reference to the *essential principles*

This document has been prepared to support the *essential principles of safety and performance* of *medical devices* or *accessories* according to ISO 16142-1:2016. This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific *essential principles* of ISO 16142-1:2016. Other means are possible. Table F.1 maps the clauses and subclauses of this document with the *essential principles* of ISO 16142-1:2016.

Table F.1 — Correspondence between the *essential principles* for non-*IVD medical devices* and this document

***Essential principle* of ISO 16142-1:2016, Annex B**	**Corresponding clause(s)/ sub-clause(s) of this document**	**Qualifying remarks/Notes**
2	—	
d)	6.6.2 a) 6)	
9.8	5.12 c)	
12.1	6.6.2 e)	Only the requirement to disclose restrictions is covered.
13.2	6.6.2 c)	
13.4	5.1	
14.4	—	
19.2	4 e), 6.6.1 e)	
20.1	6.6.1 d), 6.6.3	Only the labelling requirement is covered.
20.3	6.6.3 d) 2)	
21.1	6.6.2 a)	
21.2	6.5.2 a) 1), 6.6.2 a) 4)	
21.3	6.6.2 a) 3), 6.6.2 d)	
21.4	5.2, 6.1.6	
21.5	—	
a)	6.1.2 a)	
b)	6.1.3 a)	
c)	5.12 a)	
d)	6.1.4 a) 2), 6.2 c)	
e)	5.9 a) 4), 6.1.4 a) 3)	
f)	5.11, 6.1.3 d) 2)	
i)	6.1.3 b) 1)	
j)	6.1.3 b) 2)	
k)	6.1.3 b) 3)	
l)	6.1.4 c) 2)	
m)	5.12 b), 6.1.3 d) 5)	

Table F.1 *(continued)*

Essential principle **of ISO 16142-1:2016, Annex B**	**Corresponding clause(s)/ sub-clause(s) of this document**	**Qualifying remarks/Notes**
21.6	5.9 a) 1), 6.1.4 a) 1), 6.2 c)	
21.7	—	
a)	6.6.1 c) 1)	
b)	6.5.1 b)	
c)	5.12 a)	
g)	6.1.3 b) 1), 6.6.4 b)	
h)	6.1.3 b) 2)	
i)	6.1.3 b) 3)	
j)	5.12 b), 6.1.3 d) 5)	
k)	6.6.2 e)	
l)	6.6.2 a) 11), 6.6.2 j) 3) vii)	
n)	6.6.2 j) 3) iii)	
o)	6.5.3 c) 5), 6.6.2 g)	
p)	6.1.3 d) 4)	Inclusion of information related to restrictions on the number of reuses is addressed.
q)	6.6.2 a) 11), 6.6.2 d) 1)	
21.8	6.6.2 a) 8)	

This document has been prepared to support the *essential principles of safety and performance* of as an *IVD medical device* according to ISO 16142-2:2017. This document is intended to be acceptable for conformity assessment purposes.

Conformity with this document provides one means of demonstrating conformance with the specific *essential principles* of ISO 16142-2:2017. Other means are possible. Table F.2 maps the clauses and subclauses of this document with the *essential principles* of ISO 16142-2:2017.

Table F.2 — Correspondence between the *essential principles* for *IVD medical devices* and this document

Essential principle **of ISO 16142-2:2017, Annex B**	**Corresponding clause(s)/ subclause(s) of this document**	**Qualifying remarks/Notes**
2	—	
d)	6.6.2 a) 6)	
11.1	6.6.2 e)	Only the requirement to disclose restrictions is covered.
12.3	5.1	
17.1	4 d) 1), 4 e)	Only the requirement for information and instructions is covered.
17.3	6.6.2 d) 2)	
18.1	5.6, 5.7, 5.8, 5.10, 6.1.2 a), 6.6.2	
a)	4 e),6.6.1 e), 6.3 a)	
b)	6.1.1, 6.6.2 l)	
c)	6.6.1 a)	
d)	6.1.1 b)	

Table F.2 *(continued)*

***Essential principle* of ISO 16142-2:2017, Annex B**	**Corresponding clause(s)/ subclause(s) of this document**	**Qualifying remarks/Notes**
e)	6.6.5 e)	The requirements regarding near-*patient* testing and non-professional use are not addressed.
f)	6.6.2 a) 6)	The requirement only is covered when the *residual risks* are expressed as limitations, contraindications, precautions or warnings.
g)	5.2	
18.2	—	
a)	6.1.2 a)	
b)	6.1.3 a)	
c)	6.1.2 a)	
e)	6.1.4 a) 1), 6.1.4 a) 2), 6.2 c)	
f)	5.10 a)	
g)	5.9 a) 4), 6.1.4 a) 3), 6.1.4 c) 2) ii)	
h)	6.5.1 c)	
i)	6.1.3 b) 1)	
j)	5.12 a), 5.12 b)	
k)	6.1.3 b) 3)	
l)	6.1.3 b) 2)	
m)	5.11, 6.1.3 d) 2)	
18.3	—	
a)	6.6.1 c) 1)	
b)	6.6.2 a) 4)	
iv)	6.6.2 a) 4)	
vi)	6.6.2 a) 4)	
vii)	6.6.2 a) 4)	
i)	6.6.2 e) 1)	
ii)	6.6.2 e) 1)	
i)	6.1.3 b) 1), 6.6.4 b)	
j)	6.1.3 b) 2)	
l)	5.12 a), 5.12 b), 6.5.3 c) 5), 6.6.2 g)	
m)	6.6.2 j)	
i)	6.6.2 j) 3) i)	
ii)	6.6.2 j) 3) ii)	
iii)	6.6.2 j) 3) iii)	
iv)	6.6.2 j) 3) iv)	
v)	5.11 a), 6.1.3 d) 2) i)	
vi)	6.1.3 d) 4)	Inclusion of information related to restrictions on the number of reuses is addressed.
o)	6.6.1 e), 6.6.2 d) 7)	
q)	6.6.2 a) 11), 6.6.2 d) 1)	
r)	6.6.2 d)	

Table F.2 *(continued)*

***Essential principle* of ISO 16142-2:2017, Annex B**	**Corresponding clause(s)/ subclause(s) of this document**	**Qualifying remarks/Notes**
i)	6.6.2 d) 2)	
ii)	6.6.2 d) 3)	
iii)	6.6.2 d) 4)	
iv)	6.6.2 d) 5)	
s)	6.6.2 d) 6)	
y)	6.6.2 a) 10)	
i)	6.6.2 a) 10) i)	
ii)	6.6.2 a) 10) ii)	
iii)	6.6.2 a) 10) iii)	
z)	6.6.1 c) 1), 6.6.1 c) 2)	
aa)	6.6.2 a) 8)	

Annex G
(informative)

Reference to the general safety and performance requirements for *medical devices*

This document has been prepared to support the general safety and performance requirements of regulation (EU) 2017/745.[5] This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific indicated general safety and performance requirements of regulation (EU) 2017/745[5]. Other means are possible. Table G.1 maps the clauses and subclauses of this document with the general safety and performance requirements of regulation (EU) 2017/745.

NOTE When a general safety and performance requirement does not appear in Table G.1, it means that it is not addressed by this document.

Table G.1 — Correspondence between this document and the general safety and performance requirements for *medical devices*

General safety and performance requirements of regulation (EU) 2017/745, Annex I[5]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
4	—	
(c)	4 a), 6.6.2 a) 3), 6.6.2 a) 6)	The requirement for training is not addressed.
Last sentence	6.6.2 a) 6) ii)	
5	—	
(b)	4 e)	This requirement is covered as it relates to the *information supplied by the manufacturer*.
10.4.5	6.1.3 c), 6.6.2 j) 3) iv)	
11.8	5.12 a), 5.12 c), 6.1.3 d) 5) i) II), 6.5.3 c) 1), 6.5.3 c) 2) i) II)	
14.1	6.6.2 e)	
14.6	4 a), 4 e)	
14.7	6.6.2 a) 10)	Only the requirement to disclose safe disposal or recycling *procedures* and measures is covered.
15.1	6.6.2 c)	Only the requirement to indicate accuracy is covered.
15.2	5.1	
16.1	—	
(b)	6.6.2 j) 3) ii)	
22.1	4 a), 4 c) 2), 4 e	Only the disclosure requirement is covered.
22.3	6.6.2 d)	The requirement to warn for failure to provide a valid result is not addressed.

Table G.1 *(continued)*

General safety and performance requirements of regulation (EU) 2017/745, Annex I[5]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
23.1	4 e), 6.1.2 a) 1), 6.1.3 a), 6.1.4 b), 6.1.4 b) 1), 6.6.2 a) 3), 6.6.2 a) 5), 6.6.2 f) 2)	
(a)	4 a), 4 e), 6.3 a), 6.3 b), 6.6.1 e) 1)	
(b)	6.1.1 a)	
(c)	6.1.1 b)	
(d)	6.6.1 a) 1)	
(e)	6.6.2 l)	
(f)	6.6.5 a), 6.6.5 b), 6.6.5 c),6.6.5 d), 6.6.2 l) 1)	
(g)	4 a), 6.6.2 a) 6)	
(h)	5.2, 6.1.2 c), 6.1.2 d), 6.1.2 e) 2), 6.1.3 a) 2) ii) II), 6.1.3 c) 1), 6.1.3 c) 2), 6.1.3 c) 3), 6.1.3 c) 4), 6.1.3 d) 1) i) II), 6.1.3 d) 2) iii), 6.1.3 d) 3) ii), 6.1.3 d) 5) i) II), 6.1.3 d) 6) i), 6.1.3 d) 6) ii), 6.1.3 d) 6) iii), 6.1.3 d) 7) i), 6.1.3 e) 1), 6.1.3 f), 6.1.4 a) 1) i) II), 6.1.4 a) 2) i) II), 6.1.4 a) 3) i) II), 6.1.4 a) 4) i) II), 6.1.4 a) 4) i) III), 6.1.4 b) 1), 6.1.4 c) 1) i) II), 6.1.4 c) 2) i) I), 6.1.5 b), 6.2 b) 2) ii), 6.2 c) 1) ii), 6.5.1 b) 3) i), 6.5.1 b) 4) i) I) 2, 6.5.1 b) 4) ii) I) 2, 6.5.1 b) 4) iv) I) 2, 6.5.1 b) 4) v) I) 2, 6.5.1 b) 4) v) I) 3, 6.5.1 b) 5) i) II), 6.5.1 b) 5) ii) II), 6.5.1 b) 6) iii), 6.5.1 b) 7) ii), 6.5.3 a) 1), 6.5.3 c) 2) i) II), 6.5.3 c) 3) i) II), 6.5.3 c) 5) i), 7.1 a) 1), 7.1 a) 2), 7.3 a) 1), 7.4 a) 1)	The requirement regarding Common Specifications is not addressed.
23.2	6.1.1	
(a)	6.1.1 a), 6.1.2 a) 1), 6.6.1 c) 3)	
(b)	6.1.3 a) , 6.6.1 c) 3), 6.6.1 c) 3) i)	
(c)	6.1.2 a) 1)	
(d)	6.1.2 a) 2)	
(e)	6.1.3 d) 6), 6.1.3 d) 7), 6.5.1 b) 4) iii)	
(f)	6.1.3 c), 6.6.2 j) 3) iv)	The requirement for the disclosure of precautionary measures is not addressed.
(g)	6.1.4 a) 1), 6.1.4 a) 2)	
(h)	5.10, 6.1.4 b), 6.1.4 b) 1)	
(i)	6.1.4 a) 3), 6.5.1 b) 4) iv)	
(j)	6.1.4 a) 4) ii)	
(k)	6.1.3 b) 1)	
(l)	5.12 a), 5.12 b), 6.1.3 d) 5)	
(m)	6.1.3 b) 3), 6.1.3 b) 3) i)	
(n)	5.11 a), 6.1.3 d) 2), 6.1.3 d) 3)	

Table G.1 *(continued)*

General safety and performance requirements of regulation (EU) 2017/745, Annex I[5]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
(o)	6.1.3 d) 4)	Only the requirement for limitation of reuse is addressed.
(p)	6.1.4 e)	
23.3	—	
(a)	6.5.3 c) 4)	
(b)	6.5.3 c) 1)	
(c)	6.5.3 c) 2)	
(d)	6.5.1 b) 1)	
(h)	6.1.4 c) 2)	
(i)	6.1.4 c) 1), 6.5.3 c) 3)	
(j)	6.5.3 c) 5)	
23.4	6.6.1	
(a)	6.1.3 b) 1) i), 6.6.1 c) 1) i), 6.6.1 c) 3) i), 6.6.2 a) 11), 6.6.2 j) 3) iv), 6.6.2 m)	The requirements for the name, contains or incorporates medical substance or tissues or cells, disclosure of precautionary measures or main constituent or constituents responsible for achieving the principal intended action when using introduced substances are not addressed.
(b)	6.6.2 a) 2), 6.6.2 a) 7), 6.6.2 a) 7) i), 6.6.2 c)	
(c)	6.6.2 f) 1)	
(d)	6.6.2 f) 2)	
(e)	6.6.2 d) 1), 6.6.2 f) 2)	
(g)	6.6.2 a) 6)	
(h)	6.6.2 c)	
(i)	6.6.2 a) 11), 6.6.2 d)	
(j)	6.6.2 d) 7)	
(k)	6.6.2 d), 6.6.2 d) 1), 6.6.2 d) 2), 6.6.2 d) 3), 6.6.2 d) 4), 6.6.2 d) 5)	
1st dash	6.6.2 d) 2)	
2nd dash	6.6.2 d) 3)	
3rd dash	6.6.2 d) 4)	
4th dash	6.6.2 d) 5)	
(l)	6.6.2 g)	
(m)	6.6.2 h)	
(n)	6.6.2 i)	
(q)	6.6.2 e)	
1st dash	6.6.2 e) 1)	
2nd dash	6.6.2 e) 2)	
(r)	6.6.2 s)	
1st dash	6.6.2 s) 1), 6.6.2 s) 2) , 6.6.2 s) 4) i), 6.6.2 s) 4) ii)	
2nd dash	6.6.2 s) 4) iv)	

Table G.1 *(continued)*

General safety and performance requirements of regulation (EU) 2017/745, Annex I[5]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
(s)	6.6.2 j)	
1st dash	6.6.2 j) 3) i)	
2nd dash	6.6.2 j) 3) ii)	
3rd dash	6.6.2 j) 3) iii)	
4th dash	6.6.2 j) 3) vi), 6.6.2 r)	
5th dash	6.6.2 j) 3) vi)	
6th dash	6.6.2 j) 3) iv)	
(v)	6.6.2 a) 10) i), 6.6.2 a) 10) iii)	
1st dash	6.5.2 a) 6), 6.6.2 a) 10) i)	
2nd dash	6.5.2 a) 6), 6.6.2 a) 10) iii)	
(w)	6.6.3 b) 1)	
(y)	6.6.2 a) 8)	
(z)	6.6.2 k)	

Annex H
(informative)

Reference to the general safety and performance requirements for *IVD medical devices*

This document has been prepared to support the general safety and performance requirements of regulation (EU) 2017/746[6]. This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific indicated general safety and performance requirements of regulation (EU) 2017/746[6]. Other means are possible. Table H.1 maps the clauses and subclauses of this document with the general safety and performance requirements of regulation (EU) 2017/746.

NOTE When a general safety and performance requirement does not appear in Table H.1, it means that it is not addressed by this document.

Table H.1 — Correspondence between this document and the general safety and performance requirements for *IVD medical devices*

General safety and performance requirements of regulation (EU) 2017/746, Annex I[6]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
4	—	
(c)	4 a), 6.6.2 a) 3), 6.6.2 a) 6)	The requirement for training is not addressed.
Last sentence	6.6.2 a) 6)	
5	—	
(b)	4 a), 4 e), 6.6.1 d), 6.6.1 e), 6.6.3 c)	This requirement is covered as it relates to the *information supplied by the manufacturer*.
6	6.4	This requirement is covered as it relates to the *markings* on the *medical device*.
7	6.4	This requirement is covered as it relates to the *markings* on the *medical device*.
11.6	5.12 a), 5.12 c), 6.5.3 c) 1)	
13.1	6.6.2 e)	Only the requirement to disclose restrictions is covered.
13.6	6.6.2 a) 10)	Only the requirement to disclose safe disposal or recycling *procedures* and measures is covered.
13.7	4 d), 6.6.2 p)	
14.2	5.1	
15.3	6.6.2 d) 1), 6.6.2 d) 2), 6.6.2 j) 3) viii), 6.6.4 a) 2)	
19.1	4 d) 1), 4 e), 6.6.1 e)	Only the disclosure requirement is covered.

Table H.1 *(continued)*

General safety and performance requirements of regulation (EU) 2017/746, Annex I[6]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
19.3	6.6.2 a) 11), 6.6.2 d)	The requirement to warn for failure to provide a valid result is not addressed.
20.1	6.1.2 a) 1), 6.1.3 a) 1), 6.1.3 b), 6.5.1 b) 1), 6.6.1 c) 1), 6.6.1 c) 3), 6.6.2 a) 3)	
(a)	4 e), 6.3 a), 6.6.1 e), 6.6.5 d), 6.6.5 e)	
(b)	6.1.1 a), 6.1.1 b), 6.1.1 c) 1), 6.1.1 c) 2)	
(c)	6.1.1 b), 6.3	
(d)	6.6.1 a)	
(e)	6.6.2 l)	The exception for *IVD medical devices* intended for self-testing or near-*patient* testing is not addressed
(g)	6.6.2 a) 6)	
(h)	5.2, 5.2, 6.1.2 c), 6.1.2 d), 6.1.2 e) 2), 6.1.3 a) 2) ii) II), 6.1.3 c) 1), 6.1.3 c) 2), 6.1.3 c) 3), 6.1.3 c) 4), 6.1.3 d) 1) i) II), 6.1.3 d) 2) iii), 6.1.3 d) 3) ii), 6.1.3 d) 5) i) II) 6.1.3 d) 6) i), 6.1.3 d) 6) ii), 6.1.3 d) 6) iii), 6.1.3 d) 7) i), 6.1.3 e) 1), 6.1.3 f), 6.1.4 a) 1) i) II), 6.1.4 a) 2) i) II), 6.1.4 a) 3) i) II), 6.1.4 a) 4) i) II), 6.1.4 a) 4) i) III), 6.1.4 b) 1), 6.1.4 c) 1) i) II), 6.1.4 c) 2) i) I), 6.1.5 b), 6.1.6, 6.2 b) 2) ii), 6.2 c) 1) ii), 6.5.1 b) 3) i), 6.5.1 b) 4) i) I) 2, 6.5.1 b) 4) ii) I) 2, 6.5.1 b) 4) iv) I) 2, 6.5.1 b) 4) v) I) 2, 6.5.1 b) 4) v) I) 3, 6.5.1 b) 5) i) II), 6.5.1 b) 5) ii) II), 6.5.1 b) 6) iii), 6.5.1 b) 7) ii), 6.5.3 a) 1), 6.5.3 c) 2) i) II), 6.5.3 c) 3) i) II), 6.5.3 c) 5) i), 7.1 a) 1), 7.1 a) 2), 7.3 a) 1), 7.4 a) 1)	The requirement regarding Common Specifications is not addressed.
20.2	—	
(a)	6.1.2 a), 6.2 a), 6.5.1 b) 1)	
(b)	6.1.3 a), 6.5.1 b) 1), 6.5.1 b) 5)	
(c)	6.1.2 a) 1)	
(d)	6.1.2 a) 2)	
(f)	6.1.4 a) 1), 6.1.4 a) 2	
(g)	5.10 a), 6.1.4 b), 6.1.4 b) 1)	
(h)	5.9 a) 4), 6.1.4 a) 3), 6.5.1 b) 4) iv)	
(i)	6.1.4 a) 4) ii)	
(j)	6.5.1 c)	
(k)	6.1.3 b) 1)	
(l)	5.12 a), 5.12 b), 6.1.3 d) 5)	The requirement for special microbial state is not addressed.
(m)	4 a), 6.1.3 b) 3), 6.6.2 a) 3), 6.6.2 g)	

Table H.1 *(continued)*

General safety and performance requirements of regulation (EU) 2017/746, Annex I[6]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
(n)	6.6.5 e) 1), 6.6.5 e) 2)	The requirement for a web address is not addressed.
(o)	6.1.3 b) 2)	
(p)	5.11 a), 6.1.3 d) 2)	
(q)	6.6.3 a) 2)	The requirement as it pertains to the *instructions for use* is addressed.
20.3	6.5.3 c)	
(a)	6.5.3 c) 4)	
(b)	6.5.3 c) 1)	
(c)	6.5.3 c) 2)	
(d)	6.5.1 b) 1)	
(f)	6.5.1 b) 4) v)	
(g)	6.1.4 c) 1)	
(h)	6.5.3 c) 5)	
20.4.1	—	
(a)	6.6.1 c) 3) i)	
(b)	6.6.1 c) 3) iii), 6.6.1 c) 3) iv)	
(e)	6.6.2 a) 4), 6.6.3 a)	
(j)	6.6.2 e)	
1st dash	6.6.2 e) 1)	
2nd dash	6.6.2 e) 2)	
(k)	6.1.3 b) 1), 6.6.2 a) 12)	
(m)	6.5.2 g)	
(n)	6.6.2 j)	
(i)	6.6.2 j) 3) i)	
(ii)	6.6.2 j) 3) ii)	
(iii)	6.6.2 j) 3) iii)	
(iv)	6.6.2 j) 3) iv)	
(vi)	6.6.2 i)	
(o)	6.6.2 j) 3) v)	
(p)	6.6.2 d) 7)	
(r)	6.6.2 a) 11), 6.6.2 d) 1)	
(s)	6.6.2 d)	
1st dash	6.6.2 d) 2)	
2nd dash	6.6.2 d) 3)	
3rd dash	6.6.2 d) 4)	
4th dash	6.6.2 d) 5)	
(t)	6.6.2 d) 6)	
(x)	6.6.2 f) 2)	
(ac)	6.6.2 a) 10)	
(i)	6.6.2 a) 10) i)	
(ii)	6.6.2 a) 10) ii)	
(iii)	6.6.2 a) 10) iii)	

Table H.1 *(continued)*

General safety and performance requirements of regulation (EU) 2017/746, Annex I[6]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
(ad)	6.6.1 c) 1), 6.6.1 c) 2)	The requirement for a telephone number or fax number or website address to obtain technical assistance is not addressed.
(ae)	6.6.2 a) 8)	The requirement for address modification is not addressed.

Annex I
(informative)

Terminology — Alphabetized index of defined terms

Term	Source
accessory	3.1
accompanying information	3.2
authority having jurisdiction	ISO 16142-1:2016, 3.1
batch	3.14
batch code	3.15
batch number	3.15
benefit	ISO 14971:2019, 3.2
catalogue number	3.3
clearly legible	3.4
commercial product code	3.3
commercial product name	3.3
distributor	3.5
do not reuse	3.26
e-documentation	3.6
easily legible	3.4
electronic documentation	3.6
essential principles	ISO 16142-1:2016, 3.3
essential principles of safety and performance	ISO 16142-1:2016, 3.3
expected lifetime	3.7
expected service life	3.7
group standard	ISO 16142-1:2016, 3.4
hazard	ISO 14971:2019, 3.4
hazardous situation	ISO 14971:2019, 3.5
IFU	3.11
importer	3.8
information for safety	3.9
information supplied by the manufacturer	3.10
instructions for use	3.11
intended use	ISO 14971:2019, 3.6
IVD medical device	ISO 16142-2:2017, 3.9
label	3.12
labelled	3.12
lay	3.13
lay person	3.13
lot	3.14
lot code	3.15
lot number	3.15
manufacturer	ISO 14971:2019, 3.9

Term	Source
marked	3.16
marking	3.16
medical device	ISO 13485:2016, 3.11
medical device family	ISO 13485:2016, 3.12
model	3.17
model number	3.17
multiple patient multiple use	3.18
normal use	IEC 62366-1:2015+AMD1:2020, 3.9
package insert	3.11
patient	IEC 62366-1:2015, 3.10
pictogram	3.19
procedure	ISO 14971:2019, 3.13
process	ISO 14971:2019, 3.14
processing	3.20
product code	3.3
product name	3.3
product standard	ISO 16142-1:2016, 3.15
residual risk	ISO 14971:2019, 3.17
responsible organization	IEC 62366-1:2015, 3.12
risk	ISO 14971:2019, 3.18
risk control	ISO 14971:2019, 3.21
risk management	ISO 14971:2019, 3.24
risk management file	ISO 14971:2019, 3.25
safety sign	3.21
serial number	3.22
service personnel	3.23
shelf-life	3.24
single patient multiple use	3.25
single use	3.26
stability	3.27
sterile	3.28
symbol	3.29
technical description	3.30
UDI carrier	3.31
unique device identification carrier	3.31
usability	IEC 62366-1:2015, 3.16
usability engineering	IEC 62366-1:2015, 3.17
use environment	IEC 62366-1:2015+AMD1:2020, 3.20
use error	IEC 62366-1:2015, 3.21
use only once	3.26
use specification	IEC 62366-1:2015+AMD1:2020, 3.23
user	IEC 62366-1:2015, 3.24

Bibliography

[1] EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices*

[2] IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance +Amendment 1:2012*

[3] IMDRF/GRRP WG/N472018[2)], , Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

[4] IMDRF/GRRP WG/N52 2019[7], *Principles of Labeling for Medical Devices and IVD Medical Devices*

[5] (EU) 2017/745, (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. *OJ L 117, Official Journal of the European Union,* pp. 1-175

[6] (EU) 2017/746, (2017) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices. *OJ L 117, Official Journal of the European Union,* pp. 176-332

[7] ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[8] ISO 18113-1:2009, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

[9] ISO/IEC/TR 20007:2014, *Information technology — Cultural and linguistic interoperability — Definitions and relationship between symbols, icons, animated icons, pictograms, characters and glyphs*

[10] ISO 11139:2018, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

[11] ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

[12] ISO 14708-2:2012, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

[13] IMDRF/UDI WG/N7 2013, *UDI Guidance: Unique Device Identification (UDI) of Medical Devices*

[14] ISO 780:2015, *Packaging — Distribution packaging — Graphical symbols for handling and storage of packages*

[15] ISO 11607-1:2006, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

[16] ISO 17664 (series), *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

[17] IEC 80001-1:2010, *Application of risk management for IT-networks incorporating medical devices — Part 1: Roles, responsibilities and activities*

[18] ISO 22742:2010, *Packaging — Linear bar code and two-dimensional symbols for product packaging*

[19] Council directive 90/385/EEC, of 20 June 1990 concerning active implantable medical devices. *The Council of the European Communities, OJ L 189, Official Journal of the European Union,* pp. 17-36, including Amendments: 31993L0042 (OJ L 169 12.7.93 pp.1-43), 31993L0068 (OJ L 220 30.8.93 pp.1-22), 32003R1882 (OJ L 284 31.10.2003 pp.1-53) and 32007L0047 (OJ L 247 21.9.2007 pp.21-55)

2) Available at http://www.imdrf.org/documents/documents.asp.

[20] Council directive 93/42/EEC of 14 June 1993 concerning medical devices, *The Council of the European Communities, OJ L 169* 12.7.1993, *Official Journal of the European Union,* pp.1-43, including Amendments: 398L0079 (OJ L 331 07.12.1998 p. 1) and 300L0070 (OJ L 313 13.12.2000 p. 22)

[21] Council directive 98/79/EC of 27 October 1998 on *in vitro diagnostic medical devices, The Council of the European Communities, OJ L 331 7.12.98, Official Journal of the European Union, pp. 17-37*

[22] ISO 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

[23] ISO 639-2, *Codes for the representation of names of languages — Part 2: Alpha-3 code*

[24] ISO 639-3, *Codes for the representation of names of languages — Part 3: Alpha-3 code for comprehensive coverage of languages*

ICS 11.040.01

Price based on 72 pages