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)							

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]
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)							
6.1.2 e) 1)							
6.1.2 e) 2)			23.1 (h)	20.1 (h)			

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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)
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)

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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) I)		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) I)		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) I)		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) I)		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) I)		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) I)		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)			
6.1.4 c) 2) i) III)		5.2.14	23.1 (h), 23.2 (j), 23.3 (h)	20.1 (h)			

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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			
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)

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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		
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)							

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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)			
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

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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		
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)

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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						
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)			

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 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)							
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)							

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 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) I)							
6.6.4 c) 16) ii) I)							
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)							

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 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)	

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)	
5.3.28	6.6.2 s)	

Labelling principles of IMDRF/GRRP WG/N52:2019[4]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
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)	

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)	
e)	6.6.5 e)	The requirements regarding near-*patient* testing and non-professional use are not addressed.

Essential principle of ISO 16142-2:2017, Annex B	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
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)	
i)	6.6.2 d) 2)	
ii)	6.6.2 d) 3)	
iii)	6.6.2 d) 4)	
iv)	6.6.2 d) 5)	

Essential principle of ISO 16142-2:2017, Annex B	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
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.

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)	
(o)	6.1.3 d) 4)	Only the requirement for limitation of reuse is addressed.

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
(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)	
(s)	6.6.2 j)	
1st dash	6.6.2 j) 3) i)	

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
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.

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)	

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)	

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

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[3] IMDRF/GRRP WG/N47. 2018[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

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

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[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*

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[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*

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[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*