BS EN ISO 15223-1:2021+A1:2025

BSI Standards Publication

Medical devices — Symbols to be used with information to be supplied by the manufacturer

Part 1: General requirements

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Full document details: BS EN ISO 15223-1:2021+A1:2025

National foreword

This British Standard is the UK implementation of EN ISO 15223-1:2021+A1:2025. It is identical to ISO 15223-1:2021, incorporating amendment 1:2025. It supersedes BS EN ISO 15223-1:2021, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/210/3, General terminology and symbols for Medical Devices.

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

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UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of www.gov.uk.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Amendments/corrigenda issued since publication

Date	Text affected
30 November 2025	Implementation of ISO amendment 1:2025 with CEN/CENELEC endorsement A1:2025

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15223-1:2021+A1

November 2025

ICS 01.080.20; 11.040.01

Supersedes EN ISO 15223-1:2016

English version

Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)

Dispositifs médicaux - Symboles à utiliser avec les informations à fournir par le fabricant - Partie 1: Exigences générales (ISO 15223-1:2021)

Medizinprodukte - Zu verwendende Symbole mit durch den Hersteller bereitgestellten Informationen - Teil 1: Allgemeine Anforderungen (ISO 15223-1:2021)

This European Standard was approved by CEN on 4 June 2021.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 13 October 2021.

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European foreword

This document (EN ISO 15223-1:2021) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with Technical Committee CEN-CENELEC/ JTC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN-CENELEC shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 15223-1:2016.

This document has been prepared under a Standardization Request given to CEN and CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For the relationship with EU Directive(s) / Regulation(s), see informative Annex ZA and ZB, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

This document is an adoption of an International Standard. The definitions in applicable regulatory requirements differ from nation to nation and region to region. As a result, the definitions in this document can differ in wording from those in European Regulations. For use in support of European requirements, definitions in the European regulations for medical devices take precedence.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard “within the meaning of Annex ZA and Annex ZB”, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

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Table — Correlations between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 8601-1	--	ISO 8601-1:2019[a]
ISO 8601-2	--	ISO 8601-2:2019[a]
ISO 15223-2	--	ISO 15223-2:2010
ISO 3166-1	EN ISO 3166-1:2020	ISO 3166-1: 2020

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15223-1:2021 has been approved by CEN-CENELEC as EN ISO 15223-1:2021 without any modification.

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European foreword to Amendment 1

This document (EN ISO 15223-1:2021/A1:2025) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for products with a health purpose including medical devices" in collaboration with Technical Committee CEN-CENELEC/ JTC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This Amendment to the European Standard EN ISO 15223-1:2021 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2026, and conflicting national standards shall be withdrawn at the latest by May 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN-CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a standardization request addressed to CEN and CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA and ZB, which are an integral parts of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 15223-1:2021/Amd 1:2025 has been approved by CEN-CENELEC as EN ISO 15223-1:2021/A1:2025 without any modification.

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Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

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Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
4 (c)	5.2.6 5.2.7 5.2.8 5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 5.3.7 5.3.8 5.3.9 5.4.1 5.4.2 5.4.3 5.4.4 5.4.5 5.4.6 5.4.7 5.4.8 5.4.9 5.4.10 5.4.11 5.4.12	Partially covered: used to draw user's attention on the label to the safety information such as warnings/precautions/contraindications only for the aspects dealt with by these symbols placed in the instructions for use or accompanying information and of any residual risks and need for training for users. Not covered: does not provide further information for safety about warning/precautions/contraindications other than the ones dealt with by these symbols, nor training.
10.4.5	5.4.3 5.4.10	Partially covered: used to draw user's attention on the label to the safety information placed in the instructions for use or accompanying information of the presence of substances that are carcinogenic, mutagenic, toxic to reproduction and/or having endocrine-disrupting properties.
11.3	5.2.1 5.2.2 5.2.3 5.2.4	Partially covered: used as part of the label to identify sterile or non-sterile medical devices. Not covered: Design, manufacture, and packaging.

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	5.2.5 5.2.7 5.2.10	
11.8	5.2.1 5.2.3 5.2.4 5.2.5 5.2.7 5.2.10	Covered: used as part of the label to distinguish between identical sterile and non-sterile medical devices.
14.1	5.4.3 5.4.4	Partially covered: used to draw user's attention on the labelling to the safety information in the instructions for use.
22.1	5	Partially covered: used to convey specific label information in a format that is easy for the intended user to understand. Not covered: the design and manufacture for appropriate performance, taking user's skills into account; the understanding and application of the instructions for use.
23.1 (first sentence)	5.1.1 5.1.3 5.1.5 5.1.6 5.1.7 5.1.10 5.1.11	Partially covered: used to identify the medical device and its manufacturer.
23.1 (a)	5	Partially covered: used to convey label information in a format that is easy to understand. Not covered: the medium, format, content, legibility and location of the label, instructions for use, and accompanying information; the technical knowledge, experience, and training of the intended user; understanding of the intended use, drawings, or diagrams.
23.1 (b)	5	Partially covered: used to provide label information directly on a medical device in a symbol format that would be otherwise impracticable by use of text. Not covered: the information that is required on the label and/or medical device, but that can be placed on the medical device or the packaging.

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23.1 (c)	5	Partially covered: used to provide label information in a human readable format that would be otherwise impracticable by use of text. Not covered: machine-readable information.
23.1 (g)	5.4.3 5.4.4	Partially covered: may be used to draw user's attention on the label to the safety information concerning limitation, contra-indications, precautions, or warnings. Not covered: the residual risks required to be communicated by way of limitations, contra-indications, precautions, or warnings.
23.1 (h)	4.2 5	Covered: symbols used to convey information in combination with risk management. Symbols addressed in 5 are used on labels without a description of the symbol required in the instructions for use or accompanying information to convey information. Not covered: the use of other symbols will require a description of the symbol in the instructions for use or accompanying information.
23.2 (b)	5.1.6 5.1.10 5.7.10	Partially covered: used as part of the label information to identify the medical device and the packaging contents. Not covered: the intended purpose of the medical device.
23.2 (c)	5.1.1	Partially covered: used as part of the label information to identify the manufacturer and registered place of business (address). Not covered: the trade name or registered trademark.
23.2 (d)	5.1.2	Covered: used as part of the label information to identify the authorised representative and registered place of business (address).
23.2 (e)	5.4.6 5.4.7 5.4.8 5.4.9	Covered: used as part of the label information to identify that the medical device contains or incorporates a medicinal substance, including a human blood or plasma derivative; or tissues or cells, or their derivatives, of human origin; or tissues or cells of animal origin, or their derivatives.
23.2 (f)	5.4.3	Partially covered: used to draw user's attention

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	5.4.10	on the label to the safety information placed in the instructions for use or accompanying information of the presence of substances that are carcinogenic, mutagenic, toxic to reproduction and/or have endocrine-disrupting properties.
23.2 (g)	5.1.5 5.1.7	Covered: used to replace the words 'LOT NUMBER' and 'SERIAL NUMBER'
23.2 (h)	5.7.10	Partially covered: symbol used to indicate the UDI carrier
23.2 (i)	5.1.4	Covered: used to indicate the time limit for use or implant of the medical device, accompanied by the date (to include at least year and month).
23.2 (j)	5.1.3 5.1.11	Covered: used to indicate the date of manufacture for the medical device, accompanied by the date (to include at least year and month).
23.2 (k)	5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 5.3.7 5.3.8 5.3.9	Covered: used to indicate information that the medical device is: fragile. restricted for safety by exposure to the indicated lower limit temperature value. needs protection from sunlight and other light sources, or heat and radioactive sources, or moisture. Partially covered: used to indicate that for safe use and effectiveness the medical device has: an upper limit of temperature accompanied by the temperature value. upper and lower limits of temperature accompanied by the upper and lower temperature values. upper and lower limits of humidity accompanied by the upper and lower humidity values. upper and lower limits of pressure accompanied by the upper and lower pressure values.
23.2 (l)	5.2.1 5.2.2 5.2.3 5.2.4 5.2.5 5.2.10	Covered: used on the label to specify an indication of the medical device's sterile state and the method of sterilization. If symbol 5.2.1 is used, the GSPR is only partially covered as this symbol does not indicate the method of sterilization.

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23.2 (m)	5.2.6 5.2.7 5.2.8 5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 5.3.7 5.3.8 5.3.9 5.4.1 5.4.2 5.4.3 5.4.4 5.4.5 5.4.10	Partially covered: used to draw user's attention on the label to the more detailed warnings or precautions found in the instructions for use or accompanying information.
23.2 (n)	5.4.2	Covered: used to specify on the label that the medical device is intended for single use.
23.2 (q)	5.7.7	Covered: used to specify on the label that the device is a medical device. Not covered: for labelling of devices intended for clinical use only.
23.2 (s)	5.1.5 5.1.7	Covered: used to replace the words 'LOT NUMBER' and 'SERIAL NUMBER'
23.3 (a)	5.2.11 5.2.12 5.2.13 5.2.14	Covered: used to specify on the label of the medical device that the packaging is sterile packaging (sterile barrier system).
23.3 (b)	5.2.1 5.2.2 5.2.3 5.2.4 5.2.5 5.2.10	Covered: used as part of the label to identify the medical device is sterile.
23.3 (c)	5.2.2 5.2.3 5.2.4 5.2.5 5.2.10	Covered: used to specify on the label the method of sterilization.

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23.3 (d)	5.1.1	Covered: used as part of the label information to identify the manufacturer and registered place of business (address).
23.3 (h)	5.1.3 5.1.11	Covered: used to indicate the date of manufacture for the medical device, accompanied by the date (to include at least year and month).
23.3 (i)	5.1.4	Covered: used to indicate the time limit for use or implant of the medical device, accompanied by the date (to include at least year and month).
23.3 (j)	5.2.8 5.4.3	Covered: used to draw user's attention on the label to the more detailed warnings or precautions found in the instructions for use or accompanying information if the packaging is damaged or opened.
23.4 (a)	5.1.1 5.2.1 5.2.2 5.2.3 5.2.4 5.2.5 5.2.10 5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 5.3.7 5.3.8 5.3.9 5.4.2 5.4.3 5.4.4 5.4.6 5.4.7 5.4.8 5.4.9 5.4.10	Covered: used as part of the label information to identify that the medical device contains or incorporates: a medicinal substance, including a human blood or plasma derivative (23.2 (e)). tissues or cells, or their derivatives, of human origin (23.2 (e)). tissues or cells of animal origin, or their derivatives (23.2 (e)). Covered: used to indicate information that the medical device is: fragile (23.2 (k)). restricted for safety by exposure to the indicated lower limit temperature value, (23.2 (k)). needs protection from sunlight and other light sources, or heat and radioactive sources, or moisture (23.2 (k)). intended for single use (23.2 (n)). Covered: used on the label to specify an indication of the medical device's sterile state and the method of sterilization (23.2 (l)). Partially covered: used to indicate that for safe use and effectiveness the medical device has: an upper limit of temperature accompanied by the temperature value (23.2 (k)). upper and lower limits of temperature accompanied by the upper and lower temperature values (23.2 (k)). upper and lower limits of humidity accompanied by the upper and lower humidity values (23.2

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		(k)). upper and lower limits of pressure accompanied by the upper and lower pressure values (23.2 (k)). Partially covered: used as part of the label information to identify the manufacturer and registered place of business (address) (23.2 (c)). Partially covered: Symbol 5.2.1 is used to indicate that a medical device is sterile but does not indicate method of sterilization (23.2(l)). Partially covered: used to draw user's attention on the label to the safety information placed in the instructions for use or accompanying information of the presence of substances that are hazardous, carcinogenic, mutagenic, toxic to reproduction and/or have endocrine-disrupting properties (23.2 (f)). Not covered: the trade name or registered trademark (23.2 (a)), (23.2 (c)). Not covered: the method of sterilization is not specified in symbol 5.2.1 so cannot be used to meet 23.2(l) (see symbols 5.2.2, 5.2.3, 5.2.4, 5.2.5).
23.4 (l)	5.2.8 5.4.3	Partially covered: used on the label to draw user's attention to the more detailed warnings or precautions found in the instructions for use or accompanying information if the packaging is damaged or opened. Not covered: instructions in the event of damage or unintentional opening.
23.4 (p)	5.4.2	Partially covered: used on the label to specify that the medical device is intended for single use. Not covered: information and technical factors that could pose a risk if re-used.
23.4 (aa)	5.1.1 5.1.5 5.1.7 5.1.10 5.7.3	Partially covered: used on information provided to the patient to draw attention to the more detailed information regarding the implanted medical device. Not covered: specific information regarding the

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	5.7.4 5.7.5 5.7.6 5.7.7 5.7.10	implanted medical device.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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Table ZA.2 — Normative references from clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 8601-1	ISO 8601-1:2019 ISO 8601-1:2019/A1:2022	Date and time — Representations for information interchange Part 1: Basic rules	-
ISO 8601-2	ISO 8601-2:2019	Date and time — Representations for information interchange Part 2: Extensions	-
ISO 15223-2	ISO 15223-2:2010	Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied Part 2: Symbol development, selection and validation	-
ISO 3166-1	ISO 3166-1: 2020	Codes for the representation of names of countries and their subdivisions Part 1: Country code	EN ISO 3166-1:2020

Table ZA.3 — Terms and definitions from clause 3 of this document which differ from a definition of the same term set out in Regulation (EU) 2017/745

Reference in Regulation (EU) 2017/745	Definition in Regulation (EU) 2017/745	Reference in Clause 3	Definition in Clause 3
2.1	'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment oralleviation of disease, diagnosis, monitoring, treatment, alleviation of, or	3.12	medical device instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

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	compensation for, an injury or disability, investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: devices for the control or support of conception; products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.		investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include: disinfection substances; aids for persons with disabilities; devices incorporating animal or human tissues, or both; devices for in vitro fertilization or assisted reproduction technologies.
2.13	‘label’ means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;	3.8	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

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			appearing on the item. Note 4 to entry: See Figure 1
2.14	'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;	3.7	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 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 with jurisdiction. Note 5 to entry: See Figure 1.
2.30	'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;	3.10	manufacturer natural or legal person with responsibility for the design or manufacture, or both, of a medical device with the intention of making the medical device available for use, under his or her name; whether or not such a medical device is designed or manufactured, or both, by that person themselves or on their behalf by another person(s) Note 1 to entry: The natural or legal person has ultimate legal responsibility for ensuring compliance with all applicable

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			regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction. Note 2 to entry: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions. Note 3 to entry: "Design or manufacture, or both", may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose. Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device. Note 6 to entry: An authorized representative, distributor or

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			importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer. Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design, manufacture, or both, of that accessory is considered to be a manufacturer.
2.33	'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market;	3.5	importer natural or legal person who imports a medical device or accessory into a locale that was manufactured in another locale for the purposes of marketing
2.34	'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;	3.4	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 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.

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Annex ZB
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning in vitro diagnostic medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/746, the differences shall be indicated in the Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/746, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the In vitro Diagnostic Regulation (EU) 2017/746).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/746. This means that risks have to be 'reduced as far as possible', 'reduced to a level as low as reasonably practicable', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'prevented' or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

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Table ZB.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/746 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
4 (c)	5.2.6 5.2.7 5.2.8 5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 5.3.7 5.3.8 5.3.9 5.4.1 5.4.2 5.4.3 5.4.4 5.4.5 5.4.6 5.4.7 5.4.8 5.4.9 5.4.10 5.4.11 5.4.12	Partially covered: used on the label to draw user's attention to the safety information placed in the instructions for use or accompanying information and of any residual risks and need for training for users. Not covered: does not provide information for safety nor training.
11.2	5.2.1 5.2.2 5.2.3 5.2.4 5.2.5 5.2.7 5.2.10	Partially covered: used as part of the label to identify sterile or non-sterile *in vitro* diagnostic medical devices. Not covered: Design, manufacture, and packaging.
11.6	5.2.1 5.2.7	Covered: used as part of the label to distinguish between identical sterile and non-sterile *in vitro* diagnostic medical devices.

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