EUROPEAN STANDARD

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EN ISO 15223-1

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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.

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

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

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.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.

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.

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 a Commission's standardisation request 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].

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.

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 This Annex ZA is based on normative references according to the table of references in the European Foreword, replacing the references in the core text.

NOTE 4 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.

Table ZA.1 — – Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117]

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	5.4.35.4.10	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 5.2.5 5.2.7 5.2.10	Partially covered: used as part of the label to identify sterile or non-sterile medical devices. Not covered: Design, manufacture, and packaging.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
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.
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.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
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)	5.1.65.1.10 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)	5.4.35.4.10	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 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).

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
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.
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.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
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.
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.

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
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 (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).

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
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 5.7.4 5.7.5 5.7.6 5.7.7 5.7.10	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 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.

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 a Commission's standardisation request to provide one voluntary means of conforming to the requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning in vitro diagnostic medical devices [OJ L 117].

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.

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 This Annex ZB is based on normative references according to the table of references in the European Foreword, replacing the references in the core text.

NOTE 4 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.

Table ZB.1 — – Correspondence between this European standard and Annex I of Regulation (EU) 2017/746 [OJ L 117]

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.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
19.1	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.
20.1 (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.
20.1 (b)	5	Partially covered: used to provide label information directly on an *in vitro* diagnostic 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 *in vitro* diagnostic medical device but that can be placed on the device or the packaging.
20.1 (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.
20.1 (g)	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.
20.1 (h)	4.2 5	Covered: symbols used to convey information in combination with risk management. Symbols addressed in 5.1 may be used on labels without a description of the symbol required in the instructions for use or accompanying information to convey information. Not covered: use of other symbols will require a description of the symbol in the instructions for use or accompanying information.
20.2 (b)	5.1.6 5.1.7 5.7.10	Partially covered: used as part of the label information to identify the *in vitro* diagnostic medical device and the packaging contents. Not covered: the intended purpose of the *in vitro* diagnostic medical device.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
20.2 (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.
20.2 (d)	5.1.2	Covered: used as part of the label information to identify the authorised representative and registered place of business (address).
20.2 (e)	5.5.1 5.5.6	Covered: used as part of the label information to identify that the device is an *in vitro* diagnostic medical device, or that the *in vitro* diagnostic medical device is intended for performance studies.
20.2 (f)	5.1.5 5.1.7	Covered: used to replace the words 'LOT NUMBER' and 'SERIAL NUMBER'.
20.2 (g)	5.7.10	Covered: used to indicate the UDI carrier.
20.2 (h)	5.1.4	Covered: used to indicate the time limit for use, accompanied by the date (to include at least year and month, and if relevant, day).
20.2 (i)	5.1.3	Covered: used to indicate the date of manufacture for the *in vitro* diagnostic device, accompanied by the clearly identifiable date.
20.2 (j)	5.5.5	Covered: used to express the net quantity of contents or numerical count. Not covered: the contents by weight or volume.
20.2 (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 *in vitro* diagnostic 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 *in vitro* diagnostic medical device has: an upper limit of temperature accompanied by the temperature value. a lower 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.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
20.2 (l)	5.2.1 5.2.2 5.2.3 5.2.4 5.2.5 5.2.7 5.2.10	Covered: used on the label to specify an indication of the *in vitro* diagnostic medical device's non-sterile or sterile state and the method of sterilization. If symbol 5.2.1is used, the GSPR is only partially covered as this symbol does not indicate the method of sterilization.
20.2 (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 on the label to draw user's attention to the more detailed warnings or precautions found in the instructions for use or accompanying information.
20.2 (n)	5.4.3	Partially covered: used on the label to draw user's attention to the electronic instructions for use (eIFU).
20.2 (p)	5.4.2	Covered: used on the label to specify that the *in vitro* diagnostic medical device is intended for single use.
20.2 (t)	5.1.5 5.1.7	Covered: used to replace the words 'LOT NUMBER' and 'SERIAL NUMBER' for each *in vitro* diagnostic medical device and separate component.
20.3 (a)	5.2.11 5.2.12 5.2.13 5.2.14	Covered: used to specify on the label of the *in vitro* diagnostic medical device that the packaging is sterile packaging (sterile barrier system).

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
20.3 (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 *in vitro* diagnostic medical device is sterile.
20.3 (c)	5.2.2 5.2.3 5.2.4 5.2.5 5.2.10	Covered: used on the label to specify the method of sterilization.
20.3 (d)	5.1.1	Covered: used as part of the label information to identify the manufacturer and registered place of business (address).
20.3 (f)	5.1.3	Covered: used to indicate the date of manufacture for the *in vitro* diagnostic medical device, accompanied by the date (to include at least year and month).
20.3 (g)	5.1.4	Covered: used to indicate the time limit for use, accompanied by the date (to include at least year and month and if relevant, day).
20.3 (h)	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.
20.4.1 (b)	5.1.6 5.7.10	Partially covered: used to indicate details necessary to uniquely identify the *in vitro* diagnostic medical device
20.4.1 (d)	5.5.1 5.5.6	Covered: used to identify that the device is an *in vitro* diagnostic medical device Not covered: indication that *in vitro* diagnostic medical device is for performance study only.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
20.4.1 (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 *in vitro* diagnostic 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. Covered: used to indicate that for safe use and effectiveness the medical device has: an upper limit of temperature accompanied by the temperature value. a lower 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
20.4.1 (l)	5.4.1 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 the time limit for use, accompanied by the date (to include at least year and month and if relevant, day). Covered: used to indicate information that the *in vitro* diagnostic 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. Covered: used to indicate that for safe use and effectiveness the medical device has: an upper limit of temperature accompanied by the temperature value. a lower 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

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
20.4.1 (m)	5.2.1 5.2.2 5.2.3 5.2.4 5.2.5 5.2.8 5.2.10	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. If symbol 5.2.1 is used, the GSPR is only partially covered as this symbol does not indicate the method of sterilization.)
20.4.1 (n)	5.4.3	Covered: used to indicate on the label that the device is intended for single use. 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 if the packaging is damaged or opened. Not covered: detailed warnings, precautions, contraindications, measures to be taken and limitations of use regarding the *in vitro* diagnostic medical device.
20.4.1 (o)	5.4.1	Partially covered: used to draw user's attention on the label to the more detailed warnings or precautions found in the instructions for use regarding potentially infectious material. Not covered: detailed warnings or precautions.
20.4.1 (ad)	5.1.1	Partially covered: may be used as part of the instructions for use to identify the manufacturer and registered place of business (address). This can also be accompanied by the telephone/fax/website information. Not covered: the trade name or registered trademark.

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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Foreword

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

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

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

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 15223-1:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

— addition of 20 *symbols* that were validated as per ISO 15223-2;

— addition of 5 *symbols* previously published in ISO 7000, ISO 7001 and IEC 60417;

— deletion of the defined term "labelling";

— inclusion of defined terms from ISO 20417, ISO 13485 and ISO 14971;

— expansion of the examples given in Annex A;

— information about European regulations has been moved to informative notes throughout.

A list of all parts in the ISO 15223 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Medical device *manufacturers* and others in the supply chain must provide specific information on the *medical device* itself, as part of the packaging, or in the *accompanying information*. For simplicity and to avoid translation of text, this information can be provided as *symbols* that have a specific meaning. This document does not specify the information that needs to be provided, but does specify internationally recognized *symbols* for the provision of this specific information.

The *symbols* included in this document have been published in ISO 7000, ISO 7001, IEC 60417 or have been subjected to a formal *symbol* validation process.

This document is intended to be used by *manufacturers* of *medical devices* who market products in countries where there are specific language requirements. These *symbols* allow for a consistent portrayal of information. It can also be used by consumers or end users of *medical devices* who draw their supplies from a number of sources and can have varied language capabilities.

In this document, the conjunctive "or" is used as an "inclusive or"; so a statement is true if any combination of the conditions is true.

Terms defined in Clause 3 are shown in *italic type* throughout the document.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability;

— "must" indicates an external constraint that is not a requirement of the document.

Information marked as "NOTE" is intended to assist the understanding or use of the document. "Notes to entry" used in Clause 3 provide additional information that supplements the terminological data and can contain provisions relating to the use of a term.

Symbols added during the revision of this document were placed at the end of the pertinent section of Table 1 to preserve the numbering of existing *symbols* and facilitate easy referencing of existing *symbols* in other documents.

NOTE Numbers given in square brackets throughout the document refer to the Bibliography.

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

Part 1: General requirements

1 Scope

This document specifies *symbols* used to express information supplied for a *medical device*. This document is applicable to *symbols* used in a broad spectrum of *medical devices*, that are available globally and need to meet different regulatory requirements.

These *symbols* can be used on the *medical device* itself, on its packaging or in the *accompanying information*. The requirements of this document are not intended to apply to *symbols* specified in other standards.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country code*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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

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

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

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g. CD/DVD-ROM, USB stick, website).

Note 4 to entry: See Figure 1.

Note 5 to entry: The *label* can include the information on the packaging of the medical device.

Note 6 to entry: e-documentation can include any or all types of information supplied by the manufacturer partially or entirely.

Note 7 to entry: Marketing information is also known as promotional material.

Note 8 to entry: There is guidance or rationale related to accompanying information in ISO 20417:2021,[15] Annex A.

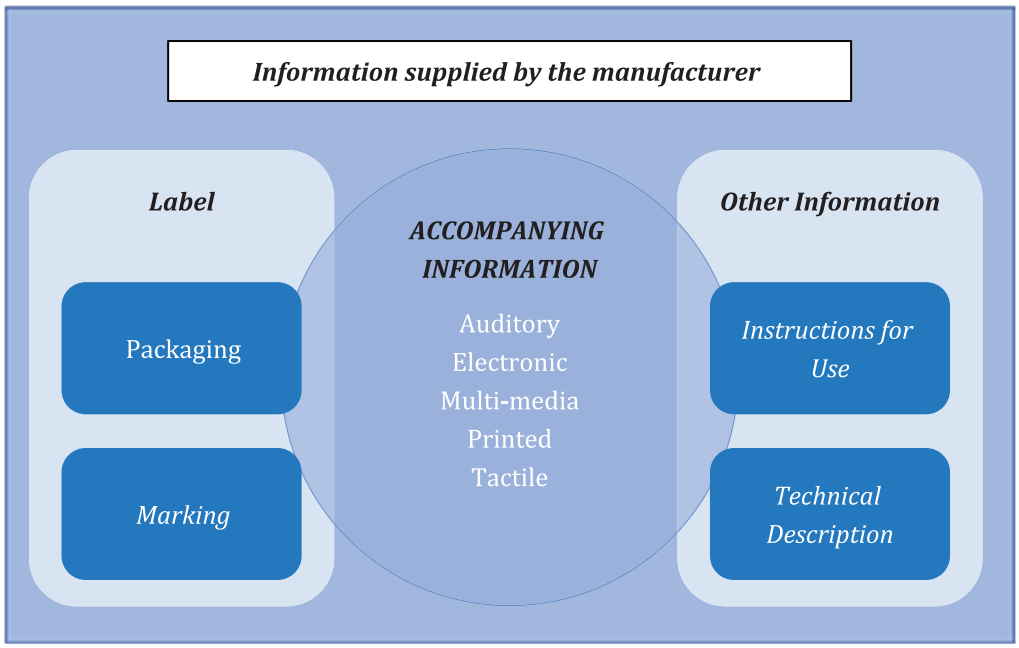


Figure 1 — Relationship of terms used to describe *information supplied by the manufacturer*

[SOURCE: ISO 20417:2021,[15] 3.2, modified — The following text has been removed from the graphic: "Scope of ISO 20417", defined term reference numbers and a side box containing information outside the scope of ISO 20417. Note 8 to entry has been added.]

3.2
catalogue number
commercial product name
commercial product code
value given by the *manufacturer* to identify a specific *medical device* or accessory as it relates to its form/fit, function and process (i.e. manufacturing processes requiring differentiation for the end user)

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

Note 2 to entry: For the purposes of this document, *commercial product code* should not be confused with the US FDA, "product code" or procode classification.

Note 3 to entry: Synonyms for *catalogue number* are "reference number" or "reorder number".

Note 4 to entry: See ISO 20417:2021, Figure 2.

[SOURCE: ISO 20417:2021,[15] 3.3, modified — The cross-reference in Note 4 to entry has been revised to be external to this document.]

3.3
description
normative text which defines the purpose, the application and the use of the *symbol* (3.19)

[SOURCE: IEC 80416-1:2008,[19] 3.2, modified — "and optional product area" has been removed.]

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*.

[SOURCE: ISO 20417:2021,[15] 3.5]

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

[SOURCE: ISO 20417:2021,[15] 3.8]

3.6
information supplied by the manufacturer
information related to the identification and use of a *medical device* or accessory, in whatever form provided, intended to ensure the safe and effective use of the *medical device* or accessory

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

Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from *information supplied by the manufacturer*. However, some *authorities having jurisdiction* (defined in ISO 16142-1:2016,[9] 3.1) can consider such supplemental information as *information supplied by the manufacturer*.

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

Note 4 to entry: See Figure 1.

Note 5 to entry: There is guidance or rationale related to information supplied by the manufacturer in Annex A.

[SOURCE: ISO 20417:2021,[15] 3.10, modified — The cross-reference in Note 2 to entry has been added. Note 5 to entry has been added.]

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.

[SOURCE: ISO 20417:2021,[15] 3.11]

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 appearing on the item.

Note 4 to entry: See Figure 1.

[SOURCE: ISO 20417:2021,[15] 3.12]

3.9
lot number
batch code
batch number
lot code
production control containing a combination of letters or numbers associated with a single lot or batch

Note 1 to entry: The title of *symbol* 5.1.5 uses the synonym *batch code.*

[SOURCE: ISO 20417:2021,[15] 3.15, modified — Note 1 to entry has been added.]

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 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 *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*.

[SOURCE: ISO 14971:2019,[8] 3.9]

3.11
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *medical device* or accessory

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from "direct *marking*" as commonly described in unique device identification (UDI) standards and regulations. A UDI "direct *marking*" is a type of *marking*.

Note 3 to entry: See Figure 1.

[SOURCE: ISO 20417:2021,[15] 3.16]

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;

— 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.

[SOURCE: ISO 13485:2016,[7] 3.11]

3.13
model number
model
letters, numbers or a combination of these assigned by a *manufacturer* to distinguish by function or type, a particular *medical device, accessory* or *medical device family* from another

Note 1 to entry: See ISO 20417:2021, Figure 2.

[SOURCE: ISO 20417:2021,[15] 3.17, modified — The cross-reference in Note 1 to entry has been revised to be external to this document.]

3.14
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2019,[8] 3.18]

3.15
serial number
production control containing a combination of letters or numbers, selected by the *manufacturer*, intended for quality control and identification purposes to uniquely distinguish an individual *medical device* from other *medical devices* with the same *catalogue number* or *model number*

[SOURCE: ISO 20417:2021,[15] 3.22]

3.16
single patient multiple use
<*medical device*, accessory> intended by the *manufacturer* to be reused on an individual patient for multiple uses

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

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

[SOURCE: ISO 20417:2021,[15] 3.25]

3.17
single use
do not re-use
use only once
<*medical device*, accessory> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

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

[SOURCE: ISO 20417:2021,[15] 3.26]

3.18
sterile
free from viable microorganisms

[SOURCE: ISO 20417:2021,[15] 3.28]

3.19
symbol
graphical representation appearing on the *label* or associated documentation, or both, of a *medical device* that communicates *characteristic information* without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

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

[SOURCE: ISO 20417:2021,[15] 3.29]

4 General requirements

4.1 Future *symbols*

a) Future *symbols* proposed for inclusion in this document shall be validated in accordance with ISO 15223-2. *Symbols* registered under ISO 7000, ISO 7010, or IEC 60417 are exempt.

b) Any *symbol* proposed for inclusion in this document shall be applicable to a range of *medical devices* and have global or regional applicability.

4.2 Requirements for usage

a) When a need to use *symbols* as an appropriate method for conveying information essential for the proper use of a *medical device* is identified, the *symbols* given in Table 1 may be marked on the *medical device*, appear on its packaging or in *information supplied by the manufacturer*.

NOTE ISO and IEC maintain an online database of graphical *symbols* for use on equipment, which contains the complete set of graphical *symbols* included in ISO 7000, ISO 7001 and IEC 60417 available at https://www.iso.org/obp/ui/#home. This database shows each graphical *symbol* and identifies it by a reference number and a *title*. The graphical *symbols* are available in different formats (e.g. AI, DWG, EPS) and some additional data, as applicable, is provided.

b) The *manufacturer* shall determine the appropriate size for the *symbol* to be legible for its intended function.

NOTE 1 This document does not specify colours or minimum size for the *symbols* in Table 1, nor does it specify the relative size of *symbols* and that of indicated information.

NOTE 2 Guidance on the application of graphical *symbols* is found in IEC 80416-3:2002+A1:2011 [20].

NOTE 3 Guidance on the use of the general prohibition *symbol* and the negation *symbol* is found in Annex B.

c) All dates and times presented in association with *symbols* shall use the conventions set out in ISO 8601-1 and ISO 8601-2.

4.3 Other *symbols*

Other standards specify additional *symbols* that are applicable to particular kinds or groups of *medical devices* or to particular situations. The bibliography provides examples of sources for additional *symbols*.

5 *Symbols*

a) When appropriate, information essential for proper use shall be indicated on the *medical device*, its packaging, or in the *accompanying information* by using the corresponding *symbols* given in Table 1.

b) A *manufacturer* may use any appropriate *symbol*.

NOTE 1 Table 1 has been organized into *symbol* categories for ease of use. The category into which a *symbol* is grouped does not have any significance as far as usage is concerned. The order of appearance of *symbols* and the categories in which they are placed are not prioritized. Examples of the use of *symbols* can be found in Annex A.

NOTE 2 Each *symbol* in the ISO/IEC *symbols* database (available at https://www.iso.org/obp/ui/#home) has a reference number and registration date. This information is given in the final column of Table 1.

Table 1 — *Symbols* to convey *medical device* information

Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.1 Manufacture						
5.1.1 	*Manufacturer*	Indicates the *medical device manufacturer*	This *symbol* shall be accompanied by the name and address of the *manufacturer* adjacent to the *symbol*.	NOTE 1 This *symbol* is used to indicate information that is required in Europe and can be required by other authorities having jurisdiction. NOTE 2 For use in Europe the full definition of "*manufacturer*" is given in EU Regulations 2017/745[23] and 2017/746.[24] Other jurisdictions can have unique definitions. NOTE 3 The date of manufacture, as well as the name and address of the *manufacturer*, can be combined in one *symbol*.	—	ISO 7000-3082 2011-10-02
5.1.2 	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union	This *symbol* shall be accompanied by the name and address of the authorized representative, adjacent to the *symbol*.	NOTE 1 This *symbol* is used to indicate information that is required in the European Community/European Union. NOTE 2 Additional guidance can be found in ISO 20417 [15], ISO 18113-1 [10], ISO 18113-2 [11], ISO 18113-3 [12], ISO 18113-4 [13] and ISO 18113-5 [14]. NOTE 3 If multiple *symbols* (i.e. Authorized Representative, *Importer*, *Distributor*, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated, and all applicable *symbols* can be grouped together next to the single address.	—	N/A

Table 1 — *Symbols* to convey *medical device* information *(continued)*

Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.1.3 	Date of manufacture	Indicates the date when the *medical device* was manufactured	This *symbol* shall be accompanied by a date to indicate the date of manufacture. This shall be expressed in accordance with ISO 8601-1. The date shall be located adjacent to the *symbol*.	—	The use of this *symbol* precludes the use of *symbol* 5.1.11 with a date of manufacture.	ISO 7000-2497 2004-01-15
5.1.4 	Use-by date	Indicates the date after which the *medical device* is not to be used	This *symbol* shall be accompanied by a date to indicate that the *medical device* should not be used after the end of the year, month or day shown. The date shall be expressed in accordance with ISO 8601-1. The date shall be located adjacent to the *symbol*.	NOTE Synonyms for "use-by date" are "use by", "expiry date" and "expiration date".	—	ISO 7000-2607 2004-01-15
5.1.5 	*Batch code*	Indicates the *manufacturer'sbatch code* so that the batch or lot can be identified	This *symbol* shall be accompanied by the *manufacturer's batch code adjacent to the symbol.*	NOTE Synonyms for "*batch code*" are "*lot number*", "lot code" and "*batch number*".	—	ISO 7000-2492 2004-01-15

Table 1 — *Symbols* to convey *medical device* information *(continued)*

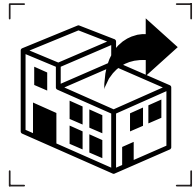
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.1.6 	*Catalogue number*	Indicates the *manufacturer'scatalogue number* so that the *medical device* can be identified	This *symbol* shall be accompanied by the *manufacturer's catalogue number* adjacent to the *symbol*.	NOTE Synonyms for "*catalogue number*" are "*commercial product name", "commercial product code", stock keeping unit,* "reference number" and "reorder number".	—	ISO 7000-2493 2004-01-15
5.1.7 	*Serial number*	Indicates the *manufacturer'sserial number* so that a specific *medical device* can be identified	This *symbol* shall be accompanied by the *manufacturer's serial number* adjacent to the *symbol*.	—	—	ISO 7000-2498 2004-01-15
5.1.8 	*Importer*	Indicates the entity importing the *medical device* into the locale	This *symbol* shall be accompanied by the name and address of the importing entity adjacent to the *symbol.*	NOTE If multiple *symbols* (i.e. Authorized Representative, *Importer*, *Distributor*, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.	—	ISO 7000-3725 2019-11-01
5.1.9 	*Distributor*	Indicates the entity distributing the *medical device* into the locale	This *symbol* shall be accompanied by the name and address of the distributing entity adjacent to the *symbol.*	NOTE If multiple *symbols* (i.e. Authorized Representative, *Importer*, *Distributor*, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.	—	ISO 7000-3724 2019-11-01

Table 1 — *Symbols* to convey *medical device* information *(continued)*

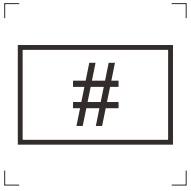
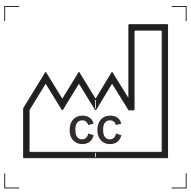
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.1.10 	*Model number*	Indicates the *model number* or type number of a product	This *symbol* shall be accompanied by the *model number* of the product adjacent to the *symbol*.	—	—	IEC 60417-6050 2012-07-14
5.1.11 	Country of manufacture	To identify the country of manufacture of products	In the application of this *symbol*, the "CC" shall be replaced by either the two-letter country code or the three letter country code defined in ISO 3166-1. The date of manufacture may be added adjacent to this *symbol*.	NOTE Not all authorities with jurisdiction recognize the two letter or three letter country codes found in ISO 3166-1.	The use of this *symbol* with a date of manufacture precludes the use of *symbol* 5.1.3.	IEC 60417-6049 2012-07-14
5.2 Sterility						
5.2.1 	*Sterile*	Indicates a *medical device* that has been subjected to a sterilization process	—	—	Use of this *symbol* precludes the use of *symbols* 5.2.2 to 5.2.5 or 5.2.10.	ISO 7000-2499 2004-01-15

Table 1 — *Symbols* to convey *medical device* information *(continued)*

Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.2.2 	Sterilized using aseptic processing techniques	Indicates a *medical device* that has been manufactured using accepted aseptic techniques	—	NOTE Aseptic techniques can include filtration.	Use of this *symbol* precludes the use of *symbol* 5.2.1.	ISO 7000-2500 2004-01-15
5.2.3 	Sterilized using ethylene oxide	Indicates a *medical device* that has been sterilized using ethylene oxide	—	—	Use of this *symbol* precludes the use of *symbol* 5.2.1.	ISO 7000-2501 2004-01-15
5.2.4 	Sterilized using irradiation	Indicates a *medical device* that has been sterilized using irradiation	—	—	Use of this *symbol* precludes the use of *symbol* 5.2.1.	ISO 7000-2502 2004-01-15
5.2.5 	Sterilized using steam or dry heat	Indicates a *medical device* that has been sterilized using steam or dry heat	—	—	Use of this *symbol* precludes the use of *symbol* 5.2.1.	ISO 7000-2503 2004-01-15

Table 1 — *Symbol*s to convey *medical device* information *(continued)*

Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.2.6 	Do not resterilize	Indicates a *medical device* that is not to be resterilized	—	—	This *symbol* is only to be used when there is an accompanying *Sterilesymbol* (5.2.1 to 5.2.5 or 5.2.10). This *symbol* is not to be used on reusable *medical devices* that are intended to be sterilized between uses.	ISO 7000-2608 2004-01-15
5.2.7 	Non-*sterile*	Indicates a *medical device* that has not been subjected to a sterilization process	—	—	This *symbol* should only be used to distinguish between identical or similar *medical devices* sold in both *sterile* and non-*sterile* conditions. Use of this symbol precludes the use of symbols 5.2.1 to 5.2.5 and 5.2.10.	ISO 7000-2609 2004-01-15

Table 1 — *Symbols* to convey *medical device* information *(continued)*

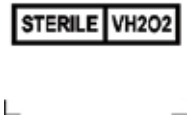
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.2.8 	Do not use if package is damaged and consult *instructions for use*	Indicates that a *medical device* that should not be used if the package has been damaged or opened and that the user should consult the i*nstructions for use* for additional information	—	NOTE 1 This *symbol* can also mean "Do not use if the product *sterile* barrier system or its packaging is compromised". NOTE 2 For products that do not have *instructions for use*, the recommendation to consult them does not apply.	—	ISO 7000-2606 2004-01-15
5.2.9 	*Sterile* fluid path	Indicates the presence of a *sterile* fluid path within the *medical device* in cases when other parts of the *medical device*, including the exterior, might not be supplied *sterile*	The method of sterilization shall be indicated in the empty portion of the symbol, as appropriate. The part of the *medical device* that is *sterile* shall be identified in the *information supplied by the manufacturer*.	—	—	ISO 7000-3084 2011-10-05
5.2.10 	Sterilized using vaporized hydrogen peroxide	Indicates a *medical device* that has been sterilized using vaporized hydrogen peroxide	—	NOTE The use of this *symbol* in Europe is explained in EN 556-1:2001,[21] 4.1 and the associated note.	Use of this *symbol* precludes the use of *symbol* 5.2.1.	N/A

Table 1 — *Symbols* to convey *medical device* information *(continued)*

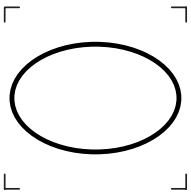
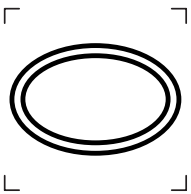
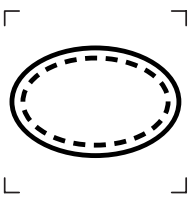
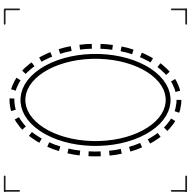
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.2.11 	Single *sterile* barrier system	Indicates a single *sterile* barrier system	This *symbol* shall be placed adjacent to or in combination with *symbol* 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10.	NOTE 1 A solid line identifies a *sterile* barrier system. NOTE 2 Additional information on *sterile* barrier systems can be found in ISO 11607-1 [5] and ISO 11607-2 [6].	—	ISO 7000-3707 2019-10-18
5.2.12 	Double *sterile* barrier system	Indicates two *sterile* barrier systems	This *symbol* shall be placed adjacent to or in combination with *symbol* 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10.	NOTE 1 A double solid line indicates a double *sterile* barrier system. NOTE 2 Additional information on *sterile* barrier systems can be found in ISO 11607-1 [5] and ISO 11607-2 [6].	—	ISO 7000-3704 2019-10-18
5.2.13 	Single *sterile* barrier system with protective packaging inside	Indicates a single *sterile* barrier system with protective packaging inside	This *symbol* shall be placed adjacent to or in combination with *symbol* 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10.	NOTE 1 The protective packaging located inside the *sterile* barrier system is designed to prevent damage to the contents or to help with aseptic presentation. It does not provide a microbial barrier to maintain sterility. NOTE 2 Additional information on *sterile* barrier systems can be found in ISO 11607-1 [5] and ISO 11607-2 [6].	—	ISO 7000-3708 2019-10-18
5.2.14 	Single *sterile* barrier system with protective packaging outside	Indicates a single *sterile* barrier system with protective packaging outside	This *symbol* shall be placed adjacent to or in combination with *symbol* 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10.	NOTE 1 The protective packaging located outside the *sterile* barrier system is designed to prevent damage to the *sterile* barrier system and the contents. The protection can be against physical hazards, particulate contamination or other environmental hazards, but it does not include a microbial barrier. NOTE 2 Additional information on *sterile* barrier systems can be found in ISO 11607-1 [5] and ISO 11607-2 [6].	—	ISO 7000-3709 2019-10-18

Table 1 — *Symbols* to convey *medical device* information *(continued)*

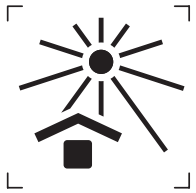
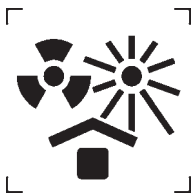
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.3 Storage						
5.3.1 	Fragile, handle with care	Indicates a *medical device* that can be broken or damaged if not handled carefully	—	—	—	ISO 7000-0621 2014-06-04
5.3.2 	Keep away from sunlight	Indicates a *medical device* that needs protection from light sources	—	NOTE This *symbol* can also mean “Keep away from heat”.	—	ISO 7000-0624 2014-06-04
5.3.3 	Protect from heat and radio-active sources	Indicates a *medical device* that needs protection from heat and radioac-tive sources	—	NOTE 1 This *symbol* can also mean “Keep away from sunlight and radioactive sources”. NOTE 2 Radioactive sources include ionizing radiation.	—	ISO 7000-0615 2004-01-15
5.3.4 	Keep dry	Indicates a *medical device* that needs to be protected from moisture	—	NOTE This *symbol* can also mean “Keep away from rain” as referenced in ISO 7000.	—	ISO 7000-0626 2014-06-04

Table 1 — *Symbols* to convey *medical device* information *(continued)*

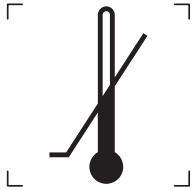
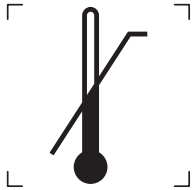
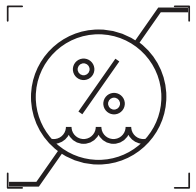
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.3.5 	Lower limit of temperature	Indicates the lower limit of temperature to which the *medical device* can be safely exposed	The lower limit of temperature shall be indicated adjacent to the lower horizontal line.	—	—	ISO 7000-0534 2004-01-15
5.3.6 	Upper limit of temperature	Indicates the upper limit of temperature to which the *medical device* can be safely exposed	The upper limit of temperature shall be indicated adjacent to the upper horizontal line.	—	—	ISO 7000-0533 2004-01-15
5.3.7 	Temperature limit	Indicates the temperature limits to which the *medical device* can be safely exposed	The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.	—	—	ISO 7000-0632 2014-06-04
5.3.8 	Humidity limitation	Indicates the range of humidity to which the *medical device* can be safely exposed	The humidity limitation shall be indicated adjacent to the upper and lower horizontal lines.	—	—	ISO 7000-2620 2004-01-15

Table 1 — *Symbols* to convey *medical device* information *(continued)*

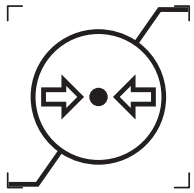
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.3.9 	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the *medical device* can be safely exposed	The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.	—	—	ISO 7000-2621 2004-01-15
5.4 Safe use						
5.4.1 	Biological *risks*	Indicates that there are potential biological *risks* associated with the *medical device*	—	NOTE This *symbol* is not to be confused with the safety sign "Biological hazard" ISO 7010-W009.	—	ISO 7000-0659 2004-01-15
5.4.2 	*Do not re-use*	Indicates a *medical device* that is intended for one *single use* only	—	NOTE Synonyms for "*Do not re-use*" are "*single use*" and "*use only once*".	—	ISO 7000-1051 2004-01-15
5.4.3 	Consult *instructions for use* or consult electronic *instructions for use*	Indicates the need for the user to consult the *instructions for use*	—	NOTE 1 Synonym for "Consult *instructions for use*" is "Consult operating instructions". NOTE 2 See also ISO 20417 [15] and the safety sign ISO 7010-M002. NOTE 3 See A.16 for examples and for use in directing users to consult the electronic *instructions for use*.	—	ISO 7000-1641 2004-01-15

Table 1 — *Symbols* to convey *medical device* information *(continued)*

Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.4.4 	Caution	Indicates that caution is necessary when operating the device or control close to where the *symbol* is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	The *symbol* variant ISO 7000-0434B (“Caution”) may be used.	—	“This *symbol* shall not be used solely to mean “consult *instructions for use*”.	ISO 7000-0434A 2004-01-15
5.4.5 	Contains or presence of natural rubber latex	Indicates the presence of dry natural rubber or natural rubber latex as a material of construction within the *medical device* or the packaging of a *medical device*	—	NOTE This *symbol* is intended to warn those people who can have allergic reactions to certain latex proteins.	This *symbol* should not be used for *medical devices* containing “synthetic rubber”.	Application of ISO 7000, symbol 2725 2005-09-08
5.4.6 	Contains human blood or plasma derivatives	Indicates a *medical device* that contains or incorporates human blood or plasma derivatives	The embedded cross may be deleted or replaced with another element appropriate with cultural requirements.	—	—	ISO 7000-3701 2010-10-18

Table 1 — *Symbols* to convey *medical device* information *(continued)*

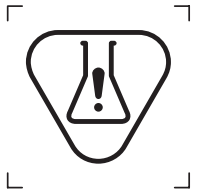
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.4.7 	Contains a medicinal substance	Indicates a *medical device* that contains or incorporates a medicinal substance	The embedded cross may be deleted or replaced with another element appropriate with cultural requirements.	—	—	ISO 7000-3702 2019-10-18
5.4.8 	Contains biological material of animal origin	Indicates a *medical device* that contains biological tissue, cells, or their derivatives, of animal origin	—	—	—	ISO 7000-3699 2019-10-18
5.4.9 	Contains biological material of human origin	Indicates a *medical device* that contains biological tissue, cells, or their derivatives, of human origin	—	—	—	ISO 7000-3700 2019-10-18
5.4.10 	Contains hazardous substances	Indicates a *medical device* that contains substances that can be carcino-genic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupt-ing properties	—	NOTE The term “substances” is used to indicate a single substance or multiple substances.	—	ISO 7000-3723 2019-11-01

Table 1 — *Symbols* to convey *medical device* information *(continued)*

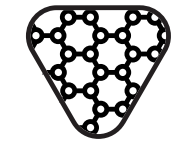
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.4.11 	Contains nano materials	Indicates a *medical device* that contains nano materials	—	—	—	ISO 7000-3703 2019-10-18
5.4.12 	*Single patient multiple use*	Indicates a *medical device* that may be used multiple times (multiple procedures) on a single patient	—	—	—	ISO 7000-3706 2019-10-18
5.5 IVD-specific						
5.5.1 	In vitro diagnostic *medical device*	Indicates a *medical device* that is intended to be used as an in vitro diagnostic *medical device*	—	NOTE For use in Europe, the full definition of "in vitro diagnostic *medical device*" is given in EU Regulation 2017/746.[24] Other jurisdictions can have unique definitions.	This *symbol* should only be used to identify in vitro diagnostic *medical-devices* or their accessories and not to specify that the *medicaldevice* is for "in vitro use".	N/A
5.5.2 	Control	Indicates a control material that is intended to verify the performance of another *medical device*	—	NOTE For negative controls, use *symbol* 5.5.3 and for positive controls use *symbol* 5.5.4.	—	N/A

Table 1 — *Symbols* to convey *medical device* information *(continued)*

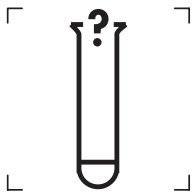
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.5.3 	Negative control	Indicates a control material that is intended to verify the results in the expected negative range	—	—	—	ISO 7000-2495 2004-01-15
5.5.4 	Positive control	Indicates a control material that is intended to verify the results in the expected positive range	—	—	—	ISO 7000-2496 2004-01-15
5.5.5 	Contains sufficient for <*n*> tests	Indicates the total number of tests that can be performed with the *medical device*	The number of tests that can be performed with the *medical device* shall appear adjacent to the *symbol*.	NOTE This symbol is suitable for use with all medical devices including in vitro diagnostic medical devices.	—	ISO 7000-0518 2004-01-15
5.5.6 	For IVD performance evaluation only	Indicates an IVD *medical device* that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use	—	NOTE 1 A synonym is "IVD for investigational use only". NOTE 2 A *medical device* that is for in vitro diagnostic performance evaluation only is not intended to be used for an in vitro diagnostic examination for medical purposes (i.e. to yield diagnostic results).	This *symbol* shall not appear jointly with *symbol* 5.5.1.	ISO 7000-3083 2011-10-03

Table 1 — *Symbols* to convey *medical device* information *(continued)*

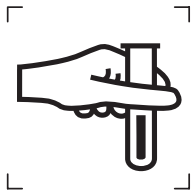
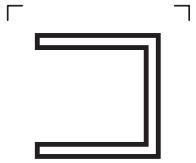
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.6 Transfusion/infusion						
5.6.1 	Sampling site	Indicates a *medical device* or blood processing application that includes a system dedicated to the collection of samples of a given substance stored in the *medical device* or blood container	—	—	This *symbol* is not to be associated with a site on a patient where samples are taken.	ISO 7000-2715 2005-09-08
5.6.2 	Fluid path	Indicates the presence of a fluid path	—	NOTE The term “fluid” means a liquid or gas.	—	ISO 7000-2722 2005-09-08
5.6.3 	Non-pyrogenic	Indicates a *medical device* that is non-pyrogenic	—	—	—	ISO 7000-2724 2005-09-08
5.6.4 	Drops per millilitre	Indicates the number of drops per millilitre	The number of drops per millilitre is specified; 20 is shown as an example and shall be replaced by the appropriate number of drops per millilitre.	—	—	ISO 7000-2726 2005-09-08

Table 1 — *Symbols* to convey *medical device* information *(continued)*

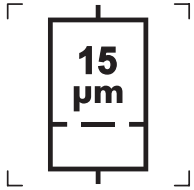
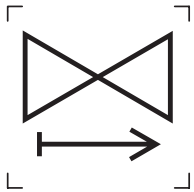
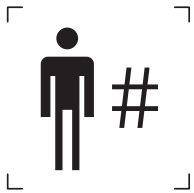
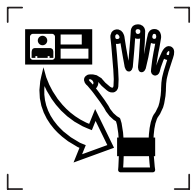
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.6.5 	Liquid filter with pore size	Indicates an infusion or transfusion system of the *medical device* that contains a filter of a particular nominal pore size	The nominal pore size of the filter is specified; 15 is shown as an example and shall be replaced by the appropriate pore size.	—	—	ISO 7000-2727 2005-09-08
5.6.6 	One-way valve	Indicates a *medical device* with a valve that allows flow in only one direction	—	NOTE It is important for the user to know that the flow is only possible in one direction and cannot be reversed.	—	ISO 7000-2728 2005-09-08
5.7 Others						
5.7.1 	Patient number	Indicates a unique number associated with an individual patient	When used, the *symbol* shall appear adjacent to the patient number or next to a space provided to record it.	NOTE The hash mark (#) is part of the *symbol*.	—	ISO 7000-2610 2004-01-15
5.7.2 	Patient name	Indicates the name of the patient	When used, the *symbol* shall appear adjacent to the patient name or next to a space provided to record it.	—	—	ISO 7000-3726 2019-11-01

Table 1 — *Symbol*s to convey *medical device* information *(continued)*

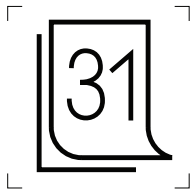
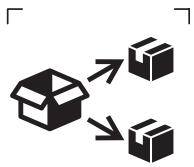
Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.7.3 	Patient identification	Indicates the identification data of the patient	When used, the *symbol* shall appear adjacent to the patient identification or next to a space provided to record it.	NOTE The question mark (?) is part of the symbol.	—	IEC 60417-5664 2002-10-07
5.7.4 	Patient information website	Indicates a website where a patient can obtain additional information on the medical product	This *symbol* shall be accompanied by the web address adjacent to the *symbol.*	NOTE Usage is to indicate location of information available to the patient.	—	ISO 7000-3705 2019-10-18
5.7.5 	Health care centre or doctor	Indicates the address of the health care centre or doctor where medical information about the patient may be found	When used, the *symbol* shall appear adjacent to the address of the health care centre or doctor or next to a space provided to record it.	NOTE The embedded cross can be deleted or replaced with another element appropriate with cultural requirements.	—	ISO 7001 PI PF 044 2013-05-31
5.7.6 	Date	Indicates the date that information was entered or a medical procedure took place	When used, the *symbol* shall appear adjacent to the date appropriate for the use of this *symbol* or next to a space provided to record it.	—	—	IEC 60417-5662 2002-10-07

Table 1 — *Symbols* to convey *medical device* information *(continued)*

Reference number and graphic	Title	*Description*	Requirements	Notes	Restrictions of use	ISO/IEC *symbol* number and registration date
5.7.7 	*Medical device*	Indicates the item is a *medical device*	—	NOTE For use in Europe the full definition of "*medical device*" is given in EU Regulation 2017/745.[23] Other jurisdictions can have unique definitions.	—	N/A
5.7.8 	Translation	Indicates that the original *medical device* information has undergone a translation which supplements or replaces the original information	This *symbol* shall be accompanied by the name and address of the entity that is responsible for the translation activity adjacent to the *symbol*.	NOTE If multiple *symbols* (i.e. Authorized Representative, *Importer*, *Distributor*, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.	This *symbol* shall only be used when the translation activity was undertaken by someone other than the *manufacturer*.	ISO 7000-3728 2019-11-01
5.7.9 	Repackaging	Indicates that a modification to the original *medical device* packaging configuration has occurred	This *symbol* shall be accompanied by the name and address of the entity that is responsible for the repackaging activity adjacent to the *symbol*.	NOTE 1 Depending on the authority having jurisdiction, additional information (i.e. date of repackaging) can be needed. NOTE 2 If multiple *symbols* (i.e. Authorized Representative, *Importer*, *Distributor*, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.	This *symbol* shall only be used when the repackaging activity was undertaken by someone other than the *manufacturer*.	ISO 7000-3727 2019-11-01
5.7.10 	Unique device identifier	Indicates a carrier that contains unique device identifier information	This *symbol* may be used when multiple data carriers are present on the label. If used, this *symbol* shall be placed adjacent to the unique device identifier carrier.	NOTE This *symbol* identifies the UDI carrier, including the AIDC and human readable information.	—	N/A

Annex A
(informative)

Guidance and examples of *symbol* use, including multiple *symbols*

NOTE 1 These examples show the requested information (e.g. Name, Address, Date, etc.) on the right side of the *symbol* or below it. If the association between the *symbol* and the requested information is unambiguous, a manufacturer can choose to put the requested information to the left or above the *symbol*.

NOTE 2 If needed, *manufacturers* may make modifications to *symbols* as explained in IEC 80416-3:2002, Clause 4.[20]

A.1 Guidance

Terms 3.1 (*accompanying information*) and 3.6 (*information supplied by the manufacturer*) are very similar and their application can vary by *authorities having jurisdiction*. ISO 20417:2021,[15] Annex A provides additional clarification.

A.2 Examples of use of *symbol* 5.1.1, "*Manufacturer*"

Name
Address

Name
Address

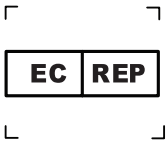
A.3 Examples of use of *symbol* 5.1.1, "*Manufacturer*", combined with 5.1.3, "Date of manufacture"

Name
Address
2019-12-01

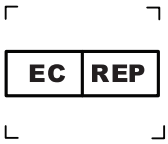
Name
Address
2019-06

A.4 Example of use of *symbol* 5.1.2, "Authorized representative in the European Community/European Union"

Examples for an authorized representative in the European Community/ European Union



Name
Address



Name
Address

A.5 Examples of use of *symbol* 5.1.3, "Date of manufacture"

2016-12-01

2016-06

A.6 Examples of use of *symbol* 5.1.4, "Use-by date"

2016-12-01

2016-06

A.7 Examples of use of *symbol* 5.1.5, "*Batch code*"

ABC123

ABC123

A.8 Examples of use of *symbol* 5.1.6, "*Catalogue number*"

ABC123

ABC123

A.9 Examples of use of *symbol* 5.1.7, "*Serial number*"

ABC123

ABC123

A.10 Examples of use of *symbol* 5.1.8, "*Importer*"

Name
Address

Name
Address

A.11 Examples of use of *symbol* 5.1.9, "*Distributor*"

Name
Address

Name
Address

A.12 Examples of use of *symbol* 5.1.11, "Country of manufacture"

NOTE 1 CC IS the two or three letter country code as defined in ISO 3166-1.

NOTE 2 Country of manufacture is determined by the *manufacturer*.

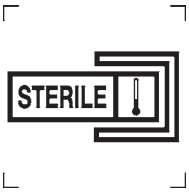
2019-06

2019-12-01

A.13 Examples of use of *symbol* 5.2.9 for "*Sterile* fluid path"

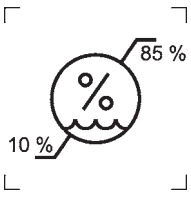
NOTE 1 *Medical device* contains a *sterile* fluid path that has been sterilized using ethylene oxide.

NOTE 2 *Medical device* contains a *sterile* fluid path that has been sterilized using irradiation.

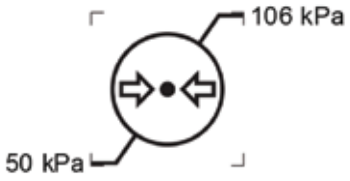


NOTE 3 *Medical device* contains a *sterile* fluid path that has been sterilized using steam or dry heat.

A.14 Examples of use of *symbol* 5.3.8, "Humidity limitation"



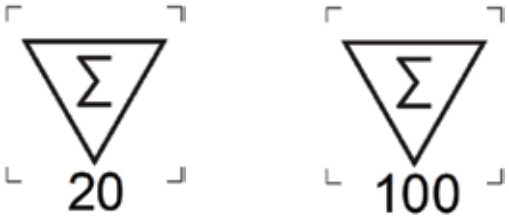
A.15 Example of use of *symbol* 5.3.9, "Atmospheric pressure limitation"



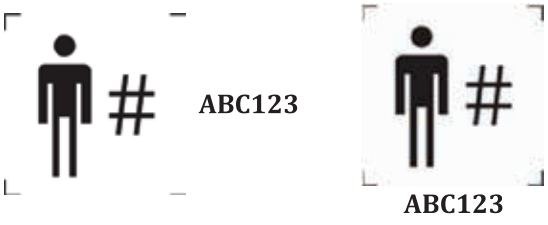
A.16 Example of use of *symbol* 5.4.3, "Consult *instructions for use* or consult electronic *instructions for use*" for an electronic *instruction for use* (e*IFU*)

NOTE The e*IFU* indicator can be a *manufacturer's* website URL or some other appropriate indication that the *instructions for use* are available in an electronic format.

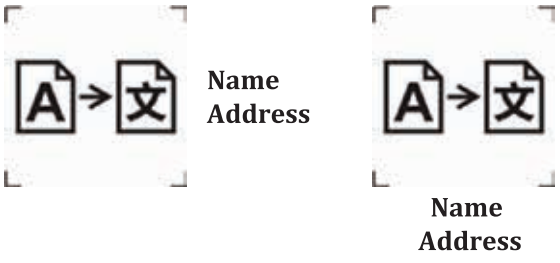
A.17 Examples of use of *symbol* 5.5.5, "Contains sufficient for <*n*> tests"



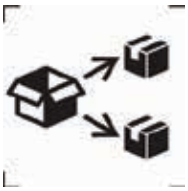
A.18 Example of use of *symbol* 5.7.1, "Patient number"



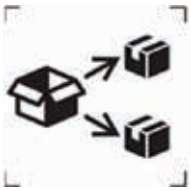
A.19 Examples of use of *symbol* 5.7.8, "Translation"



A.20 Examples of use of *symbol* 5.7.9, "Repackaging"



Name
Address



Name
Address

A.21 Examples of use of *symbol* 5.7.10, "Unique device identifier"

(01)01234567891011
(11)200622
(17)240622
(21)88888888

(01)01234567891011(11)200622(17)240622(21)88888888

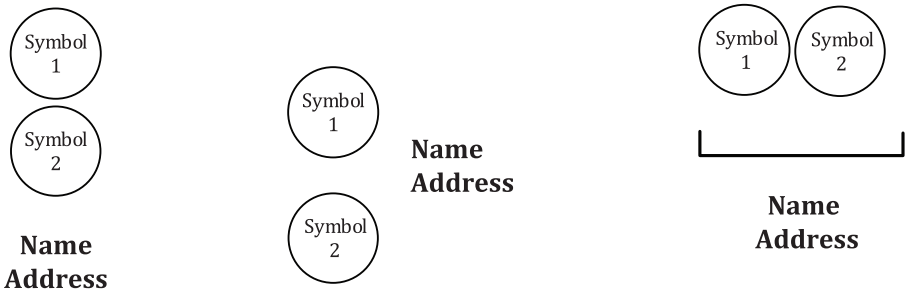
A.22 Examples of use of symbols 5.2.11 to 5.2.14 in conjunction with symbols 5.2.1 to 5.2.5, 5.2.9 or 5.2.10

A.23 Explanation on how to deal with multiple symbols used together

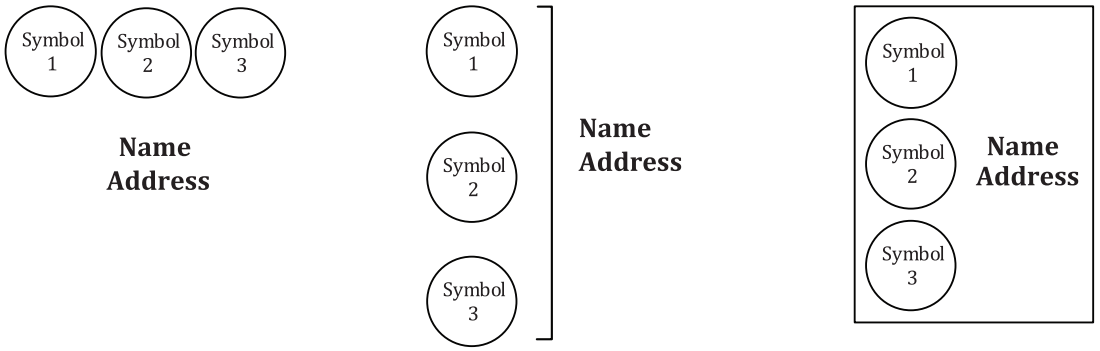
The *symbols* EC REP, *Importer*, *Distributor*, Repackaging and Translation each have a note indicating that when multiple *symbols* all apply to the same responsible entity, the name and address need not be duplicated. The following shows some of the possible ways that may be accomplished.

The intent is for the name and address to be unambiguously associated with the *symbols*. Additional graphical elements may be used for the association. Several additional graphical elements are shown below.

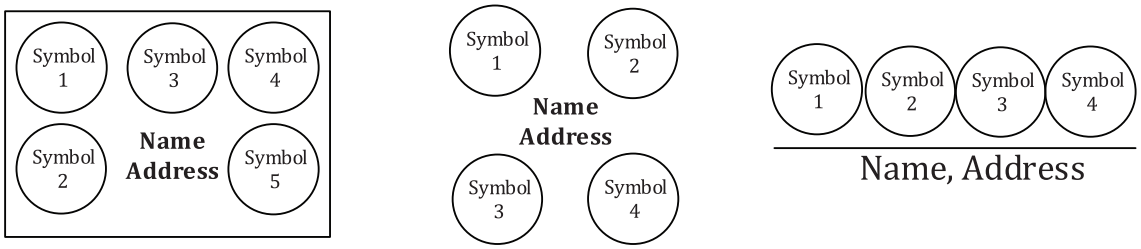
When two *symbols* apply, the *symbols* may appear grouped vertically or horizontally with the name and address adjacent to the *symbols* [i.e. either above, below, to the left, or to the right].



When three *symbols* apply, the *symbols* may appear grouped vertically or horizontally with the name and address adjacent to the symbols [i.e. either above, below, to the left, or to the right].



When four or five *symbols* apply, the symbols may appear grouped in any convenient way that is unambiguous, with the name and address adjacent to the *symbols*. [i.e. ether above, below, to the left, to the right, or with the grouping].



Annex B
(informative)

Use of general prohibition *symbol* and negation *symbol*

B.1 General prohibition *symbol*

The general prohibition *symbol* (as used in ISO 3864-1 [1]) is intended to indicate a prohibited action. For *medical device* labelling, the prohibition circle with a diagonal bar should be used to mean "do not", e.g. *symbol* 5.4.2 "Do not re-use". It is sometimes used out of context in *medical device* labels, e.g. to mean "does not contain". It is important that usage be consistent with the intended meaning so that hazards do not arise from misunderstanding.

B.2 Negation *symbol*

Manufacturers wishing to communicate the meaning "does not" or "is not" where a *symbol* expressing this meaning does not exist, should follow the method set out in IEC 80416-3:2002, Clause 7 [20] (a large "X" placed over the *symbol*). Although it is not generally recommended that this symbology be used with any of the *symbols* given in this document, the use of the negation *symbol* is permitted.

Bibliography

[1] ISO 3864-1,[1)] *Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings*

[2] ISO 7000,[1)] *Graphical symbols for use on equipment — Registered symbols*

[3] ISO 7001, [1)] *Graphical symbols — Public information symbols*

[4] ISO 7010, [1)] *Graphical symbols — Safety colours and safety signs — Registered safety signs*

[5] ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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

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

[8] ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

[9] ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

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

[11] ISO 18113-2, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use*

[12] ISO 18113-3, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use*

[13] ISO 18113-4, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing*

[14] ISO 18113-5, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing*

[15] ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

[16] IEC 60417, *(database), Graphical symbols for use on equipment*

[17] IEC TR 60878, *Graphical symbols for electrical equipment in medical practice*

[18] IEC 62570, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

[19] IEC 80416-1:2008, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols for registration*

[20] IEC 80416-3: 2002+A1:2011, *Basic principles for graphical symbols for use on equipment — Part 3: Guidelines for the application of graphical symbols*

[21] EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

1) The graphical symbol collections of ISO 7000, ISO 7001 and ISO 7010 can be previewed and purchased on the Online Browsing Platform (OBP), www.iso.org/obp.

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

[23] (EU) 2017/745, 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

[24] (EU) 2017/746, 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

National Annex NZ
(informative)

Relationship between this British Standard and the Essential Requirements of the Medical Devices Regulations 2002 (S.I. 2002 No. 618, as amended) (UK MDR 2002) aimed to be covered

This British Standard may be used to provide voluntary means of conforming to the essential requirements of the UK MDR 2002, as amended.

Once this standard is cited in the official designated standards list for medical devices, compliance with the normative clauses of this standard given in Tables NZ.1, NZ.2 and NZ.3 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirement of that Regulation.

For the purpose of using this standard in support of the requirements in the UK MDR 2002, where a definition in this designated standard differs from a definition of the same term set out in the Regulations, the definitions set out in the Regulations prevail.

Where the British Standard is an adoption of an international or a European standard, the scope of this document can differ from the scope of the Regulations that it supports. The standard can support UK regulatory requirements only to the extent of the scope of the Regulation.

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 the UK MDR 2002. 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 essential requirements.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with the applicable essential requirements of AIMDD 90/385/EEC (1, 4, 5, 8, 9 and 10), MDD 93/42/EEC (1, 2, 5, 6, 7, 8, 9, 11 and 12) and IVDD 98/79/EC (Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7) to comply with the UK MDR 2002.

NOTE 3 When an essential requirement does not appear in Tables NZ.1, NZ.2 or NZ.3, it means that it is not addressed by this standard.

Table NZ.1 — Correspondence between this British Standard and Annex 1 referenced in Part III (AIMDs) of the UK MDR 2002

Essential requirement UK MDR 2002	Clause(s)/Subclause(s) of this BS	Remarks/Notes
11	5.1.5, 5.1.6, 5.1.7	ER is covered only for indication of batch code or serial number. Components are not covered.
14, 1st paragraph	4.2, Clause 5	Provided that the symbols are used on the sterile pack or on the sales packaging.
14.1, 1st indent	5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10	Provided that the symbol is provided on the sterile pack. This ER is covered only in respect of the conditions indicated by the symbols. For other warnings, other symbols or other means of indication may be needed.
14.1, 2nd indent	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10	Provided that the symbol is provided on the sterile pack.
14.1, 3rd indent	5.1.1	Provided that the symbol is provided on the sterile pack.

Essential requirement UK MDR 2002	Clause(s)/Subclause(s) of this BS	Remarks/Notes
14.1, 7th indent	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10	Provided that the symbol is provided on the sterile pack.
14.1, 8th indent	5.1.3	Provided that the symbol is provided on the sterile pack. Active implantable medical devices must be labelled with at least the month and year of manufacture.
14.1, 9th indent	5.1.4	Provided that the symbol is provided on the sterile pack.
14.2, 1st indent	5.1.1, 5.1.2	Provided that the symbol is provided on the sales packaging. The 'trade name' of the manufacturer must not be used with this symbol.
14.2, 7th indent	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10	Provided that the symbol is provided on the sales packaging.
14.2, 8th indent	5.1.3	Provided that the symbol is provided on the sales packaging.
14.2, 9th indent	5.1.4	Provided that the symbol is provided on the sales packaging.
14.2, 10th indent	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	Provided that the symbol is provided on the sales packaging. The ER is covered only in respect of the conditions indicated by the symbols. For other conditions, other symbols or other means of indication may be needed.
14.2, 11th indent	5.4.6	Provided that the symbol is provided on the sales packaging.
15, 2nd indent	5.1.1, 5.1.2, 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, 5.4.6	Provided that the symbol is provided in the Instructions for Use relevant to: - 14.1, 1st indent: method of sterilization (5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10); - 14.1, 2nd indent: indication of sterile pack (5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10); - 14.1, 3rd indent: name and address of the manufacturer (5.1.1); - 14.1, 7th indent: declaration that the implantable device is in a sterile condition (5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10); - 14.2, 1st indent: name and address of the manufacturer and the name and address of the authorized representative (5.1.1, 5.1.2); - 14.2, 7th indent: declaration that the implantable device is in a sterile condition (5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10); - 14.2, 10th indent: conditions for transporting and storing the device (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); - 14.2, 11th indent: indication that the device contains a human blood derivative (5.4.6).
15, 8th indent	5.2.8	Provided that the symbol is provided in the instructions for use, only the warning 'Do not use the product if the product sterile barrier system or its packaging is compromised' is addressed.

Table NZ.2 — Correspondence between this British Standard and Annex 1 referenced in Part II (general medical devices) of the UK MDR 2002

Essential requirement UK MDR 2002	Clause(s)/Subclause(s) of this BS	Remarks/Notes
8.7	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.7, 5.2.10	Covered: used as part of the packaging and/or the label to distinguish between identical sterile (5.2.1, 5.2.3, 5.2.4, 5.2.5, 5.2.10) and non-sterile (5.2.7) medical devices.
13.2	4.2, 4.3, Clause 5	Only the first sentence of this ER is covered, provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.
13.3 (a)	5.1.1, 5.1.2	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.
13.3 (b)	5.1.3, 5.1.6, 5.1.10	Provided that the symbols are provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.
13.3 (c)	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9, 5.2.10	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.
13.3 (d)	5.1.5, 5.1.7	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC. If a serial number is not provided, the symbol for 'LOT' must precede the batch code.
13.3 (e)	5.1.4	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC, the 'use-by' date must be expressed as, at least, the year and the month.
13.3 (f)	5.4.2	Only the first sentence of this ER is covered, provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.
13.3 (i)	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	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC, the ER is covered only in respect of the conditions indicated by the symbols. For other conditions, other symbols or other means of indication may be needed.
13.3 (k)	5.2.6, 5.2.7, 5.2.8, 5.4.1, 5.4.4, 5.4.5, 5.4.6, 5.4.7, 5.4.8, 5.4.9, 5.4.10, 5.4.11	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC, the ER is covered only in respect of the warnings indicated by the symbols. For other warnings, other symbols or other means of indication may be needed.
13.3 (l)	5.1.3	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC. Active medical devices must be labelled with at least the year of manufacture unless a 'use-by' date (5.1.4) is given. The date of manufacture may be included in the batch or serial number (5.1.5, 5.1.7).

Essential requirement UK MDR 2002	Clause(s)/Subclause(s) of this BS	Remarks/Notes
13.3 (m)	5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC, the ER is covered only in respect of the conditions indicated by the symbols.
13.3 (n)	5.4.6	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.
13.6 (a)	5.1.1, 5.1.2, 5.1.6, 5.1.10, 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.6, 5.2.7, 5.2.8, 5.2.9, 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, 5.4.1, 5.4.2, 5.4.4, 5.4.5, 5.4.6, 5.4.10	Provided that the symbol is provided in the Instructions for Use relevant to: - 13.3 (a): the name or trade name and address of the manufacturer (5.1.1) and the authorized representative (5.1.2); - 13.3 (b): identification of the device (5.1.6, 5.1.10); - 13.3 (c): indication that the device is sterile (5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9, 5.2.10); - 13.3 (f): indication that the device is for single use (5.4.2); - 13.3 (i): special storage and/or handling conditions (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); - 13.3 (k): warnings and/or precautions to take (5.2.6, 5.2.7, 5.2.8, 5.4.1, 5.4.4, 5.4.5, 5.4.10); - 13.3 (m): method of sterilization (5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.10); - 13.3 (n): indication that the device contains a human blood derivative (5.4.6).

Table NZ.3 — Correspondence between this British Standard and Annex 1 referenced in Part IV (IVDs) of the UK MDR 2002

Essential requirement UK MDR 2002	Clause(s)/Subclause(s) of this BS	Remarks/Notes
B.8.2	4.2, Clause 5	Only the first two sentences of this ER are covered with regard to the use of symbols.
B.8.4 (a)	5.1.1, 5.1.2	In Directive 98/79/EC, the requirements of Annex I, ER B.8.4(a) refer to the IVD device label, which must show the name and address of the manufacturer and, where necessary, also of the EC authorized representative. When the IVD device is a kit (i.e. a set of several components packaged together), the kit itself shall be labelled as above with the name and address of the manufacturer and, where necessary, also of the EC authorized representative.
B.8.4 (b)	5.1.3, 5.1.6, 5.5.2, 5.5.3, 5.5.4, 5.5.5, 5.1.10	The ER is covered only in respect of the conditions indicated by the symbols.
B.8.4 (c)	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9, 5.2.10	—
B.8.4 (d)	5.1.5, 5.1.7	If a serial number is not provided, the symbol for 'LOT' must precede the batch code.

Essential requirement UK MDR 2002	Clause(s)/Subclause(s) of this BS	Remarks/Notes
B.8.4 (e)	5.1.4	The date must be expressed as the year, the month and, where relevant, the day, in that order.
B.8.4 (g)	5.5.1	—
B.8.4 (h)	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	The ER is covered only in respect of the conditions indicated by the symbols.
B.8.4 (j)	5.2.6, 5.2.8, 5.4.1, 5.4.2, 5.4.4, 5.4.5, 5.4.10	The ER is covered only in respect of the conditions indicated by the symbols.
B.8.6	5.1.5, 5.1.7	—
B.8.7 (a)	5.1.1, 5.1.2, 5.1.6, 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.6, 5.2.8, 5.2.9, 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, 5.4.1, 5.4.2, 5.4.4, 5.4.5, 5.4.10, 5.5.1, 5.5.2, 5.5.3, 5.5.4, 5.5.5	Provided that the symbol is provided in the Instructions for Use relevant to: - B.8.4 (a): name and address of the manufacturer and the name and address of the authorized representative (5.1.1, 5.1.2); - B.8.4 (b): identification of the device (5.1.6, 5.1.10, 5.5.2, 5.5.3, 5.5.4, 5.5.5); - B.8.4 (c): indication that the device is 'STERILE' (5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9, 5.2.10); - B.8.4 (g): indication of the in vitro use of the device (5.5.1); - B.8.4 (h): storage and/or handling conditions (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); - B.8.4 (j): warnings and/or precautions to take (5.2.6, 5.2.8, 5.4.1, 5.4.2, 5.4.4, 5.4.5, 5.4.10).

WARNING 1: Presumption of conformity stays valid only as long as a reference to this British Standard is maintained in the designated standards list. Users of this standard should frequently consult the latest published list.