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STN	**Zdravotnícke pomôcky Značky na používanie s informáciami poskytovanými výrobcom Časť 1: Všeobecné požiadavky (ISO 15223-1: 2021)**	**STN EN ISO 15223-1 85 0005**

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/21

Obsahuje: EN ISO 15223-1:2021, ISO 15223-1:2021

Oznámením tejto normy sa ruší
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15223-1

September 2021

ICS 01.080.20; 11.040.01

Supersedes EN ISO 15223-1:2016

English version

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

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

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

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

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

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.

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European foreword

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

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of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.

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

This document supersedes EN ISO 15223-1:2016.

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

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

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

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

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

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

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

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	5.4.3 5.4.10	Partially covered: used to draw user's attention on the label to the safety information placed in the instructions for use or accompanying information of the presence of substances that are carcinogenic, mutagenic, toxic to reproduction and/or having endocrine-disrupting properties.
11.3	5.2.1 5.2.2 5.2.3 5.2.4 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.

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.
23.1 (h)	4.2 5	Covered: symbols used to convey information in combination with risk management. Symbols addressed in 5 are used on labels without a description of the symbol required in the instructions for use or accompanying information to convey information. Not covered: the use of other symbols will require a description of the symbol in the instructions for use or accompanying information.
23.2 (b)	5.1.6 5.1.10 5.7.10	Partially covered: used as part of the label information to identify the medical device and the packaging contents. Not covered: the intended purpose of the medical device.
23.2 (c)	5.1.1	Partially covered: used as part of the label information to identify the manufacturer and registered place of business (address). Not covered: the trade name or registered trademark.
23.2 (d)	5.1.2	Covered: used as part of the label information to identify the authorised representative and registered place of business (address).
23.2 (e)	5.4.6 5.4.7 5.4.8 5.4.9	Covered: used as part of the label information to identify that the medical device contains or incorporates a medicinal substance, including a human blood or plasma derivative; or tissues or cells, or their derivatives, of human origin; or tissues or cells of animal origin, or their derivatives.

23.2 (f)	5.4.3 5.4.10	Partially covered: used to draw user's attention on the label to the safety information placed in the instructions for use or accompanying information of the presence of substances that are carcinogenic, mutagenic, toxic to reproduction and/or have endocrine-disrupting properties.
23.2 (g)	5.1.5 5.1.7	Covered: used on the label to replace the words 'LOT NUMBER' and 'SERIAL NUMBER'
23.2 (h)	5.7.10	Partially covered: symbol used on the label to indicate the UDI carrier
23.2 (i)	5.1.4	Covered: used on the label 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 on the label to indicate the date of manufacture for the medical device, accompanied by the date (to include at least year and month).
23.2 (k)	5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 5.3.7 5.3.8 5.3.9	Covered: used on the label to indicate information that the medical device is: fragile. needs protection from sunlight and other light sources, or heat and radioactive sources, or moisture. Covered: used on the label 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.
23.2 (l)	5.2.1 5.2.2 5.2.3 5.2.4	Covered: used on the label to specify an indication of the medical device's sterile state and the method of sterilization.

	5.2.5 5.2.10	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.
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 investigation only.
23.2 (s)	5.1.5 5.1.7	Covered: used on the label 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 packaging that it 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 on the packaging 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 on the packaging to specify the method of sterilization.
23.3 (d)	5.1.1	Covered: used on the packaging to identify the manufacturer and registered place of business (address).
23.3 (h)	5.1.3 5.1.11	Covered: used on the packaging 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 on the packaging 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 packaging to the more detailed warnings or precautions found in the instructions for use or accompanying information if the packaging is damaged or opened.
23.4 (a)	5.1.1 5.2.1 5.2.2 5.2.3 5.2.4 5.2.5 5.2.10 5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 5.3.7 5.3.8 5.3.9 5.4.2 5.4.3 5.4.4 5.4.6 5.4.7 5.4.8 5.4.9	Covered: used in the instructions for use 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 in the instructions for use that the medical device is: fragile (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 non-sterile or 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

	5.4.10	indicate the method of sterilization (23.2 (l)). Covered: used in the instructions for use 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)). a lower 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 in the instructions for use to identify the manufacturer and registered place of business (address) (23.2 (c)). Partially covered: used to draw user's attention to the safety information placed in the instructions for use 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)).
23.4 (l)	5.2.8 5.4.3	Partially covered: used to draw user's attention to the more detailed warnings or precautions found in the instructions for use 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 in the instructions for use 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.
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.
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 on the label to replace the words 'LOT NUMBER' and 'SERIAL NUMBER'.
20.2 (g)	5.7.10	Partially covered: used on the label to indicate the UDI carrier.
20.2 (h)	5.1.4	Covered: used on the label 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 on the label 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 on the label 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 on the label to indicate information that the *in vitro* diagnostic medical device is: fragile. 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 *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. per and lower limits of pressure accompanied by the upper and lower pressure values.
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 5.2.1 is 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 on the label 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 packaging of the *in vitro* diagnostic medical device that the packaging is sterile packaging (sterile barrier system).
20.3 (b)	5.2.1 5.2.2 5.2.3 5.2.4 5.2.5 5.2.10	Covered: used on the packaging 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 packaging to specify the method of sterilization.
20.3 (d)	5.1.1	Covered: used on the packaging to identify

		the manufacturer and registered place of business (address).
20.3 (f)	5.1.3	Covered: used on the packaging 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 on the packaging 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 packaging 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 in the instructions for use 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 in the instructions for use 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.
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 in the instructions for use to indicate information that the *in vitro* diagnostic medical device is: fragile. needs protection from sunlight and other light sources, or heat and radioactive sources, or moisture. Covered: used in the instructions for use 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.

		þer and lower limits of pressure accompanied by the upper and lower pressure values
20.4.1 (l)	5.1.4 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 in the instructions for use to indicate the time limit for use, accompanied by the date (to include at least year and month and if relevant, day). Covered: used in the instructions for use to indicate information that the *in vitro* diagnostic medical device is: fragile. needs protection from sunlight and other light sources, or heat and radioactive sources, or moisture. Covered: used in the instructions for use 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. þer and lower limits of pressure accompanied by the upper and lower pressure values
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 to the more detailed warnings or precautions found in the instructions for use if the packaging is damaged or opened. Covered: used in the instructions for use to specify an indication of the *in vitro* diagnostic medical device's non-sterile or sterile state and the method of sterilization. If symbol 5.2.1 is used, the GSPR is only partially covered as this symbol does not indicate the method of sterilization.
20.4.1 (n)	5.4.2 5.4.3	Covered: used in the instructions for use to indicate that the device is intended for single use. Partially covered: used to draw user's

		attention to the more detailed warnings or precautions found in the instructions for use. 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 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.

INTERNATIONAL STANDARD

ISO 15223-1

Fourth edition
2021-07

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

Part 1: General requirements

Dispositifs médicaux — Symboles à utiliser avec les informations à fournir par le fabricant —

Partie 1: Exigences générales

Reference number
ISO 15223-1:2021(E)

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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.

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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.

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INTERNATIONAL STANDARD **ISO 15223-1:2021(E)**

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*

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