DRAFT INTERNATIONAL STANDARD

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ISO/TC **210**

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Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —

Part 1:
General requirements

Dispositifs médicaux — Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux —

Partie 1: Exigences générales

ICS: 01.080.20; 11.040.01

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15223-1 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This third edition cancels and replaces the second edition (ISO 15223-1:2012), which has been technically revised. The principle revisions to the third edition are:

— Clause 2 – update the title of ISO 7000 and add "date of release" for each of the registered symbols to Table 1.

— Symbol 5.1.1 – modify the requirement related to the placement of the manufacturer's name and address on IVD labels.

— Symbol 5.1.2 – modify the requirement related to the placement of name and address of the authorized representative in the European Union on IVD labels.

— Symbol 5.4.3 – add information used to indicate an instruction to consult an electronic instructions for use (eIFU)

— Symbol 5.4.5 – add reference to ISO 7000-2725, "Contains or presence of".

— Annex A.15 – add examples of the placement of the eIFU indicator.

ISO 15223 consists of the following parts, under the general title *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*:

— *Part 1: General requirements*

— *Part 2: Symbol development, selection and validation*

NOTE Future symbols intended to appear in this part of ISO 15223 are to be validated in accordance with ISO 15223-2.

Introduction

This part of ISO 15223 addresses the presentation of certain items of information that are considered by regulatory authorities to be essential for the safe and proper use of medical devices. As such, the items are required to appear with the medical device in most regulatory domains. The information can be required to appear on the medical device itself, as part of the label, or provided with the medical device.

Many countries require that their own language be used to display textual information with medical devices. At the same time, manufacturers seek to take costs out of labelling by reducing or rationalizing variants. This can cause problems in relation to translation, design and logistics when multiple languages are included on a single label or piece of documentation. For example, users of medical devices labelled in a number of different languages can experience confusion and delay in locating the appropriate language.

This part of ISO 15223 proposes solutions to these problems through the use of internationally recognized symbols with precisely defined descriptions.

While compiling symbols to be included in this part of ISO 15223, ISO/TC 210 recognized the need for systematic methodology for the selection, development and validation of symbols proposed for adoption. This is the subject of ISO 15223-2.

This part of ISO 15223 is primarily intended to be used by manufacturers of medical devices who market identical products in countries where there are different language requirements for medical device labelling. It can also be of assistance to:

— distributors of medical devices or other representatives of manufacturers;

— healthcare providers responsible for training as well as those being trained;

— those responsible for post-market vigilance;

— healthcare regulatory authorities, testing organizations, certification bodies and other organizations which are responsible for implementing regulations affecting medical devices and which have responsibility for post-market surveillance; and

— consumers or end users of medical devices who draw their supplies from a number of sources and can have varied language capabilities.

Medical Devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

1 Scope

This part of ISO 15223 identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this part of ISO 15223.

This part of ISO 15223 is applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements.

These symbols may be used on the medical device itself, on its packaging or in the associated documentation. The requirements of this part of ISO 15223 are not intended to apply to symbols specified in other standards.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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 terms and definitions given in ISO 14971 and the following apply.

3.1
characteristic information
information that represents the property or properties of a symbol

3.2
description
normative text which defines the purpose, application and use of the symbol

NOTE Adapted from IEC 80416-1:2008, definition 3.2.

[1)] Available only in database format from ISO or IEC. Each symbol in the database has a "date of release". These dates are given in the ISO Registration Number column in Table 1.

3.3
label
written, printed or graphic information provided upon the medical device itself

NOTE Adapted from GHTF/SG1/N43:2005.

3.4
labelling
information supplied by the manufacturer that is provided for, associated with, or affixed to, a medical device or any of its containers or wrappers

NOTE 1 This information relates to the identification, technical description and use of the medical device, but excludes shipping documents.

NOTE 2 Some regional and national regulations refer to “labelling” as “information supplied by the manufacturer”.

3.5
symbol used in medical device labelling
graphical representation appearing on the label and/or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

NOTE The symbol can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters.

3.6
title
unique name by which a graphical symbol is identified and spoken of

NOTE Adapted from IEC 80416-1:2008, definition 3.9.

4 General requirements

4.1 Proposal of symbols for adoption

Symbols proposed for adoption in this part of ISO 15223 shall be validated in accordance with ISO 15223-2.

Any symbol proposed for adoption in this part of ISO 15223 shall be applicable to a range of medical devices and have global or regional applicability.

4.2 Requirements for usage

When risk management shows it to be appropriate for symbols to be used to convey information essential for proper use on the medical device, its packaging or in associated documentation, the symbols given in Table 1 may be used.

Symbols that are registered in ISO 7000 shall comply with the graphical representation in ISO 7000, especially with respect to relative dimensions, including relative line thickness, orientation and the absence or presence of filled or shaded areas.

NOTE 1 ISO and IEC jointly maintain an online database of graphical symbols for use on equipment, which contains the complete set of graphical symbols included in ISO 7000 and IEC 60417. In that database, each graphical symbol is identified by a reference number and contains a title (in English and French), a graphical representation in GIF and vectorised PDF format, and some additional data as applicable. Various search and navigation facilities allow for easy retrieval of graphical symbols. Information on how to subscribe in order to access this database is available through the ISO Store, the IEC Web Store or by contacting your local national standards body.

As part of risk management, the manufacturer should determine the appropriate size for the symbol to be legible for its intended function.

NOTE 2 This part of ISO 15223 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.

It is important that symbols be used properly. Guidance on appropriate use of the general prohibition symbol and the negation symbol is given in Annex B.

Before symbols are used, the manufacturer shall carry out a risk assessment that indicates that the use of the symbol does not introduce an unacceptable risk.

NOTE 3 Additional information regarding risk assessment can be found in ISO 14971.

Symbols may be used without accompanying text. Where regulations require accompanying text, the title of the symbol given in this part of ISO 15223 should be considered sufficient. All dates and times presented in association with symbols shall use the conventions set out in ISO 8601.

4.3 Other symbols

Other standards specify additional symbols that are applicable to particular kinds or groups of medical devices or to particular situations. Examples of sources for such symbols are identified in the Bibliography. This listing is not exhaustive.

5 Symbols

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

A manufacturer may use any appropriate symbol regardless of category.

NOTE 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.

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Table 1 — Symbols to convey information essential for proper use

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1 Manufacture							
5.1.1 	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	This symbol shall be accompanied by the name and address of the manufacturer (i.e. the person placing the medical device on the market), adjacent to the symbol. According to the IVD labelling standards ISO 18113-2 and ISO 18113-4, the address is required only on the device label, and, in case of an IVD kit, on the kit label, i.e. the outer container label. By contrast, the address is not required with the symbol on the label of the kit component immediate container, except when this immediate container is in practice the outer container, i.e. the kit container.	NOTE 1 This symbol is used to indicate information that is required in Europe[b]. NOTE 2 The full definition of "manufacturer" is given in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. NOTE 3 Guidance on the requirements for EU Directives 90/385/EEC and 93/42/EEC is given in EN 1041. NOTE 4 The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. NOTE 5 The relative size of the symbol and the size of the name and address are not specified.			3082 2011-10-03

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Table 1 (*continued*)

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1.2 	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.	This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol. According to the IVD labelling standards ISO 18113-2 and ISO 18113-4, the address is required only on the device label, and, in case of an IVD kit, on the kit label, i.e. the outer container label. By contrast, the address is not required with the symbol on the label of the kit component immediate container, except when this immediate container is in practice the outer container, i.e. the kit container.	NOTE 1 This symbol is used to indicate information that is required in the European Community. NOTE 2 Guidance on the requirements for EU Directives 90/385/EEC and 93/42/EEC is given in EN 1041. NOTE 3 The relative size of the symbol and the size of the name and address are not specified.			N/A