Singapore Standards Council

SINGAPORE STANDARD

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

– Part 1 : General requirements

SS 15223-1 : 2018
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(ICS 01.080.20; 11.040.01)

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– Part 1 : General requirements

This Singapore Standard was approved on 9 November 2018 by the Biomedical and Health Standards Committee under the purview of the Singapore Standards Council.

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The Biomedical and Health Standards Committee, appointed by the Standards Council, consists of the following members:

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The Technical Committee on Quality Management Systems, appointed by the Biomedical and Health Standards Committee, consists of representatives from the following organisations:

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The National Mirror Working Group on ISO/TC 210, appointed by the Technical Committee to assist in the preparation of this standard, comprises the following experts who contribute in their *individual capacity*:

		Name
Convenor	:	Dr Margam Chandrasekaran
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		Mr Paul Tan

The organisations in which the experts of the National Mirror Working Group are involved are:

Access-2-Healthcare
BioPharmaSpec UK Ltd
Sanmina Corporation Singapore
Singapore Manufacturing Federation (Medical Technology Industry Group)
SysteMED Pte Ltd
TüV SüD PSB Pte Ltd
Wise Consultants and Services Pte Ltd

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National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on ISO/TC 210 appointed by the Technical Committee on Quality Management Systems under the direction of the Biomedical and Health Standards Committee.

This standard is identical with ISO 15223-1:2017, "Medical Devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements", published by the International Organization for Standardization.

The reference to "ISO 15223-2" shall be read as "SS ISO 15223-2"

Attention is drawn to the possibility that some of the elements of this Singapore Standard may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

NOTE

1. Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions.

2. An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR.

3. Compliance with a SS or TR does not exempt users from any legal obligations

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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is 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 with the following principal revisions:

— Clause 2, updated the title of ISO 7000 and added the "date of release" for each of the registered symbols to Table 1;

— symbol 5.1.1, modified the requirement related to the placement of the manufacturer's name and address on IVD labels;

— symbol 5.1.2, modified 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, added the information used to indicate an instruction to consult an electronic instructions for use (eIFU);

— symbol 5.4.5, added the reference to ISO 7000, symbol 2725, "Contains or presence of";

— symbol 5.5.5, modified the description of the symbol and the requirement regarding use with IVD;

— A.15, added the examples of the placement of the eIFU indicator.

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

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

This corrected version of ISO 15223-1:2016 incorporates the following correction:

— in A.9, the graphical symbol of NOTE 2 has been corrected.

Introduction

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

While compiling symbols to be included in this document, 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 document 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 document 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 document.

This document 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 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 7000[1], *Graphical symbols for use on equipment — Registered symbols*

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

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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[1] The collection of ISO 7000 graphical symbols and additional information concerning their use are available at https://www.iso.org/obp/ui/#search. Each symbol in the database has a "registration date". These dates are given in the ISO Registration Number column in Table 1.