SS ISO 15223-1:2021
ISO 15223-1:2021, IDT
(ICS 01.080.20; 11.040.01)

SINGAPORE STANDARD

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

– Part 1 : General requirements

Singapore Standards Council

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The content of this Singapore Standard was approved on 16 August 2021 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

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BHSC consists of the following members:

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BHSC set up the Technical Committee on Medical Devices to oversee the preparation of this standard. The Technical Committee consists of the following members:

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Secretary	:	Mr Kevin Tan	*Singapore Manufacturing Federation – Standards Development Organisation*
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The Technical Committee set up the National Mirror Working Group on ISO/TC 210 to prepare this standard. The Working Group consists of the following experts who contribute in their *individual capacity*:

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		Mr Caleb Ng
		Mr Paul Tan

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

Access-2-Healthcare
BioPharmaSpec UK Ltd
Edwards Lifesciences (Singapore) Pte Ltd
Sanmina Corporation Singapore
Singapore Manufacturing Federation (Medical Technology Industry Group)
Stendard
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 set up by the Technical Committee on Medical Devices under the purview of BHSC.

It is a revision of SS ISO 15223-1:2018, "Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements".

This standard is an identical adoption of ISO 15223-1:2021, "Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements", published by the International Organization for Standardization.

NOTE – Reference to International/Overseas Standards are replaced by applicable Singapore Standards or Technical References.

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.

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 *symbol*s used in a broad spectrum of *medical devices*, that are available globally and need to meet different regulatory requirements.

These *symbol*s 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 *symbol*s 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.