Singapore Standards Council

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SINGAPORE STANDARD

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

– Part 1 : Symbol development, selection and validation

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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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BioPharmaSpec UK Ltd
Sanmina Corporation Singapore
Singapore Manufacturing Federation (Medical Technology Industry Group)
SysteMED Pte Ltd
TüV SüD PSB 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 15223-2:2010, “Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation”, published by the International Organization for Standardization.

The reference to “ISO 15223-1” shall be replaced by “SS ISO 15223-1”.

The comma has been used throughout as a decimal marker whereas in Singapore Standards it is a practice to use a full point on the baseline as the decimal marker.

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.

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 15223-2 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This first edition of ISO 15223-2, together with ISO 15223-1:2007, cancels and replaces ISO 15223:2000, which has been technically revised.

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*

Introduction

The ISO 15223 series of International Standards addresses symbols that can be used to convey information that is essential for the safe and proper use of medical devices. As such, in most regulatory domains the symbols are required to be presented with the device. The information can be required to be presented on the device itself, as part of the label or provided with the device.

Many countries require that their own language be used to present textual information with medical devices. This presents problems to device manufacturers and users. Faced with the requirement to produce labelling in a number of different languages, manufacturers might have to increase the size of the package or label, thus potentially increasing packaging waste, or compressing the information, thus compromising legibility. Users presented with devices labelled in a number of different languages can experience confusion and delay in locating the needed information in an appropriate language. ISO 15223-1 proposes solutions to these problems through the use of internationally recognized symbols, with precisely defined meanings, that are independent of language.

While compiling the symbols presented in ISO 15223-1, it was recognised that a systematic methodology for the development and presentation of symbols was needed. ISO/TC 210 began by formulating a “best practices” document, *Guide to the development and registration of symbols for use in the labelling of medical devices*.

When this guide was circulated to interested parties, a number of regulatory authorities were of the opinion that they would have greater confidence in the use of symbols to replace text if the best practices set out in the Guide were expressed as normative requirements in a standards document. Some of the best practices for symbols development and usage have been translated into normative requirements in ISO 15223.

Much of the information required on a medical device itself, as part of the label, or provided with the device constitutes information for safety within an integrated approach to risk management. As with any risk control measure, the manufacturer needs to verify the effectiveness of the information for safety before it can be accepted. The use of standardized symbols agreed by consensus on an international basis can address the confusion that users can experience when presented with labelling in a number of different languages. However, the proliferation of symbols without control and harmonization is undesirable and detracts from the effectiveness of using symbols to convey information for safety. In addition, some users and regulatory authorities have concerns that the unrestricted use of symbols without validation can represent a hazard.

This part of ISO 15223 includes methods for validating those candidate symbols being proposed for inclusion in ISO 15223-1. It can also be used by manufacturers and regulators for validating symbols for use with medical devices, where suitable symbols are not standardized.

This document has been prepared by ISO/TC 210 to influence the quality of symbols developed for use in labelling by establishing a process that addresses the need to ensure quality of symbols accepted in ISO 15223-1 by:

— establishing need;

— providing guidance on development of symbols;

— carrying out testing to make sure that the candidate symbol is suitable for adoption and use.

When the processes detailed in this part of ISO 15223 have been carried out, the probability of misinterpretation of symbols accepted in ISO 15223-1 is reduced.

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

Part 2: Symbol development, selection and validation

1 Scope

This part of ISO 15223 specifies a process for developing, selecting and validating symbols for inclusion in ISO 15223-1.

The purpose of this part of ISO 15223 is to ensure that symbols included in ISO 15223-1 are readily understood by the target group.

If the symbol validation process detailed in this part of ISO 15223 has been complied with, then the residual risks, as defined in ISO 14971 and IEC 62366, associated with the usability of a medical device symbol are presumed to be acceptable, unless there is objective evidence to the contrary.

This part of ISO 15223 is not restricted to symbols intended to meet regulatory requirements or specified in regulatory guidelines on labelling.

2 Normative references

The following referenced documents are indispensable for the application 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 9186-1:2007, *Graphical symbols — Test methods — Part 1: Methods for testing comprehensibility*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 80416-2, *Basic principles for graphical symbols for use on equipment — Part 2: Form and use of arrows*

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