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
Foreword

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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.