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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



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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 second edition cancels and replaces the first edition (ISO 15223-1:2007) and EN 980:2008, which have been technically revised. It also incorporates the amendment ISO 15223-1:2007/Amd.1:2008.

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.

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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.

This part of ISO 15223 constitutes a technical revision of both ISO 15223-1:2007 and EN 980:2008, combining the symbols and requirements of both standards for the first time. There has been a steady convergence of the symbol requirements in ISO 15223-1 and EN 980 over recent years, with many of the previous differences between the standards resolved. This part of ISO 15223 represents a significant advance in the safe and effective use of symbols to transcend language, giving manufacturers, regulators and others a single set of global symbols for use with medical devices.