INTERNATIONAL STANDARD

ISO 15223

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AMENDMENT 1
2002-08-01

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

AMENDMENT 1

Dispositifs médicaux — Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux
AMENDEMENT 1

Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

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 3.

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 Amendment may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to International Standard ISO 15223:2000 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices.*

Introduction

This Amendment considers certain items of information which may be considered by regulatory authorities to be essential for the safe and proper use of medical devices. As such, the items are required by the laws and regulations of certain political jurisdictions to be presented with the device. This information may be required on the device itself, part of the label of the device on its packaging, or provided with the device in an information document.

These items of information are subject to international harmonization in order to ensure agreement on information to be provided. However, there is no harmonization with regard to the language to be used when presenting this information. This presents potential problems to manufacturers, users and regulatory authorities.

Device manufacturers, desiring to minimize the indirect costs not associated with healthcare purposes, seek to minimize costs of labelling by reducing or rationalizing labeling variants. In the European Union alone, there are thirteen languages which may be required. This presents a major problem of design and logistics. In addition, technical translation can present difficulties in transferring the precise meaning from one language to another.

Users may be presented with devices labelled in a number of different languages. This can cause confusion and delay in locating the appropriate language. It can also create confusion as to the precise meanings for multilingual users.

Regulatory authorities might be presented with labelling not in their national language and might have difficulty in ascertaining the safety and fitness for use of a device required in emergencies or other exceptional circumstances.

This Amendment proposes solutions to these problems through the use of internationally recognized symbols, with precisely defined meanings that transcend language.

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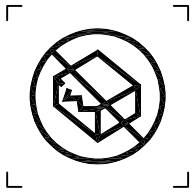
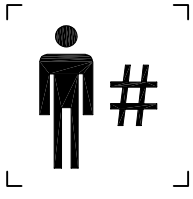
Page 5, Table 1

Add the following symbols to Table 1.

No.	Symbol	Referent
3.25	 ISO 7000-2608	Do not re-sterilize
3.26	 ISO 7000-2609	Non-sterile
3.27	 ISO 7000-2606	Do not use if package is damaged
3.28		*In vitro* diagnostic device
3.29	 ISO 7000-2610	Patient number

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