# INTERNATIONAL STANDARD

# ISO 15223-1

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**AMENDMENT 1**
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## Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —

## Part 1: General requirements

## AMENDMENT 1

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

*Partie 1: Exigences générales*

*AMENDEMENT 1*

Reference number
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## Foreword

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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.

Amendment 1 to ISO 15223-1:2007 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

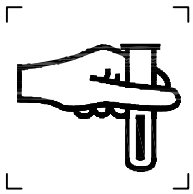
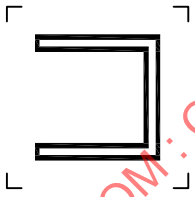
# Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —

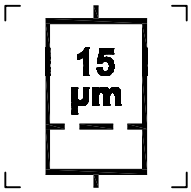
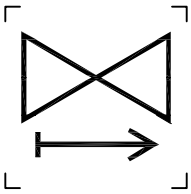
## Part 1: General requirements

## AMENDMENT 1

*Page 8, Table 1*

Add the following symbols to Table 1.

| No. | Symbol | Title | ISO 7000 or IEC 60417 registration number |
|---|---|---|---|
| 5.32 |  | Sampling site | ISO 7000-2715 |
| 5.33 |  | Fluid path | ISO 7000-2722 |
| 5.34 |  | Non-pyrogenic | ISO 7000-2724 |
| 5.35 |   | Contains or presence of natural rubber latex<br><br>NOTE This symbol should be used only when natural rubber latex is a material of construction within the device or the packaging of a device. It is intended to warn those people who may have allergic reactions to certain proteins in natural rubber latex. This symbol should not be used for devices containing "synthetic" rubber. | Derived from ISO 7000-2725 |

| No. | Symbol | Title | ISO 7000 or IEC 60417 registration number |
|---|---|---|---|
| 5.36 |  | Drops per millilitre<br><br>NOTE On medical devices: to indicate the number of drops per millilitre. The number of drops per millilitre is specified; “20” is shown as an example and should be replaced by the correct number of drops per millilitre. | ISO 7000-2726 |
| 5.37 |  | Liquid filter with pore size<br><br>NOTE On medical devices: to indicate that the infusion or transfusion system contains a liquid filter in various sizes. The nominal pore size of the filter is specified; “15” is shown as an example and should be replaced by the correct pore size. | ISO 7000-2727 |
| 5.38 |  | One-way valve | ISO 7000-2728 |