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Amd12008, Medical devices  
Symbols to be used with  
medical device labels,  
labelling and ISO 15223  
12012, Medical devices  
Symbols to be used with  
medical device labels,  
labelling and info DMD13\_2 -  
MDR og Labelling*

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*Biocompatibility: Applying  
the New ISO 10993 Standards*

## **Introduction to Medical Device Labeling Symbols**

*Software Development*

*According to IEC 62304 - A  
Real-World Perspective -  
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ISO 9001:2015 (Latest  
Quality Management System)  
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Intermediate English -  
Lesson 12 - Speaking and  
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15223-2:2010 is to ensure that symbols included in ISO 15223-1 are readily understood by the target group. If the symbol validation process detailed in ISO 15223-2:2010 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.

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ISO - ISO 15223-2:2010 -  
Medical devices – Symbols to  
be ...

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that symbols included in ISO  
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understood by the target  
group. If the symbol  
validation process detailed  
in ISO 15223-2:2010 has been  
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to be acceptable, unless  
there is objective evidence  
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ISO 15223-2:2010 -

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Description / Abstract: ISO 15223-2, 1st Edition, January 15, 2010 - Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol development, selection and validation. This part of ISO 15223 specifies a process for developing, selecting and validating symbols for inclusion in ISO 15223-1.

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ISO 15223-2 : Medical devices - Symbols to be used



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with ... Medical Device Symbols

BS ISO 15223-2:2010 Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied. Symbol development, selection and validation. The ISO 15223 series of standards addresses symbols that can be used to convey information that is essential for the safe and proper use of medical devices.

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BS ISO 15223-2:2010 - BSI - Standards

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understood by the target group. If the symbol validation process detailed in ISO 15223-2:2010 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 ...

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symbols for inclusion in ISO 15223-1. The purpose of ISO 15223-2:2010 is to ensure that symbols included in ISO 15223-1 are readily understood by the target group.

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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.

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AAMI/ISO 15223-2:2010

Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 2: Symbol development, selection and validation. standard by Association for the Advancement of Medical Instrumentation/International Org. for Standardization, 08/30/2010. View all product details

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ISO 15223-2 was prepared by



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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.

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Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Amendment 2 ... 95.99  
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Revisions / Corrigenda. Now  
withdrawn ISO 15223:2000/Amd  
2:2004 Revised by ISO  
15223-1:2007 ISO  
15223-2:2010; Got a  
question? ...

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ISO - ISO 15223:2000/Amd  
2:2004 - Medical devices ...  
ISO 15223-1:2016 is  
applicable to symbols used  
in a broad spectrum of  
medical devices, which are  
marketed globally and  
therefore need to meet  
different regulatory  
requirements. These symbols  
may be used on the medical  
device itself, on its  
packaging or in the

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