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ISO 15223-1 was

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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.

**ISO**  
**15223-1:2012(en),**

*Page 4/25*

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1 2012 Laptops  
**Medical devices ?  
Symbols to be used**

...

ISO 15223-1:2012 identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of ISO 15223-1:2012. ISO 15223-1:2012 is applicable to symbols

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used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements.

## **ISO - ISO**

### **15223-1:2012 -**

### **Medical devices —**

### **Symbols to be ...**

BS EN ISO

15223-1:2012

identifies requirements for symbols used in medical device

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labelling that convey information on the safe and effective use of medical devices. It lists symbols that satisfy the requirements of the standard and is applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements.

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**15223-1:2012**

**Medical devices.**

**Symbols to be used**

...

EN ISO 15223-1:2012

Superseded View

Superseded By

Superseded A

superseded Standard is

one, which is fully

replaced by another

Standard, which is a

new edition of the

same Standard.

**EN ISO**

**15223-1:2012 |**



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**Medical devices -  
Symbols to be used**

...

ISO 15223-1:2012 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 associated documentation.

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**EN ISO** Reviews

**15223-1:2012**

ISO/DIS 15223-1 3.5  
symbol used in medical  
device labelling  
graphical  
representation  
appearing on the label  
(3.3) and/or associated  
documentation of a  
medical device that  
communicates  
characteristic  
information (3.1)  
without the need for  
the supplier or receiver

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of the information to  
have knowledge of the  
language of a  
particular nation or  
people

**Symbols to be used  
on labelling (ISO  
15223) Information  
to ...**

BS EN ISO  
15223-1:2012 BRITISH  
STANDARD National  
foreword This British  
Standard is the UK  
implementation of EN  
ISO 15223-1:2012. It

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supersedes BS EN 980:2008 which will be withdrawn on 31 January 2013. The UK participation in its preparation was entrusted to Technical Committee CH/210/3, General terminology and symbols for Medical Devices.

## **Medical devices — Symbols to be used with medical device**

...

BS EN ISO  
*Page 12/25*

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15223-1:2016: Title:

Medical devices.

Symbols to be used with medical device labels, labelling and information to be supplied. General requirements: Status: Current, Work in hand: Publication Date: 31 December 2016:

Normative

References(Required to achieve compliance to this standard) ISO 8601, ISO 15223-2, ISO 7000

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**BS EN ISO  
15223-1:2016  
Medical devices.  
Symbols to be used**

...

ISO 15223-1:2016(en)  
... (ISO 15223-1:2012),  
which has been  
technically revised with  
the following principal  
revisions: Clause 2,  
updated the title of ISO  
7000 and added the  
date of release for  
each of the registered  
symbols to Table 1;

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**ISO 7** Reviews

**15223-1:2016(en),  
Medical devices ?  
Symbols to be used**

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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

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itself, on its packaging  
or in the associated  
documentation.

**ISO - ISO  
15223-1:2016 -  
Medical devices —  
Symbols to be ...**  
Productos sanitarios.  
Símbolos a utilizar en  
las etiquetas, el  
etiquetado y la  
información a  
suministrar. Parte 1:  
Requisitos generales.  
(ISO 15223-1:2016,  
Versión corregida  
*Page 16/25*



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2017-03). Medical  
2017-Revision  
devices - Symbols to  
be used with medical  
device labels, labelling  
and information to be  
supplied - Part 1:  
General requirements  
(ISO 15223-1:2016 ...

**UNE-EN ISO  
15223-1:2017  
Productos  
sanitarios. Símbolos  
a ...**

EN ISO 15223-1:2012  
The New Standard  
refers to symbols to be

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used with medical device labels, labelling and information to be supplied with medical devices. The Standard's provisions are applicable to all medical devices falling within the scope of EU directives on medical devices.

## **Revision of EU Standard on symbols for medical devices ...**

This part of ISO 15223

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identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this part of ISO 15223.

**EVS-EN ISO**  
**15223-1:2012 -**  
**Estonian Centre for**  
**Standardisation**

DIN EN ISO 15223-1 -

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2017-04

Medizinprodukte - Bei  
Aufschriften von  
Medizinprodukten zu  
verwendende Symbole,  
Kennzeichnung und zu  
liefernde Informationen  
- Teil 1: Allgemeine  
Anforderungen (ISO  
15223-1:2016,  
korrigierte Fassung  
2017-03); Deutsche  
Fassung EN ISO  
15223-1:2016, mit CD-  
ROM. Jetzt informieren!

**DIN EN ISO 15223-1 -**  
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**2017-04 - Beuth.de**

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.

**Medical devices —  
Symbols to be used  
with medical device**

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BS EN ISO  
15223-1:2012 (CD-  
ROM)

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15223-1:2012 (CD-  
ROM)**

Udgivet: 2012-08-31.

Godkendelsesdato:  
2012-08-01.

Tilbagetrækningsdato:  
2017-01-11.

Internationale  
relationer : EN ISO  
15223-1:2012 IDT ISO  
15223-1:2012 IDT. ICS:  
01.080.20 - Grafiske

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symboler til brug på  
specielt udstyr

11.040.01 - Medicinsk  
udstyr. Generelt  
Varenummer: M240675

### **DS/EN ISO**

### **15223-1:2012 -**

### **Webshop Dansk**

### **Standard**

EN ISO 15223-1 will  
replace EN 980 as the  
recognized standard  
for symbols to be used  
in medical device  
labeling. Moreover, two  
of the most important

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standards for  
manufacturers in the  
European Community,  
ISO 13485 and ISO  
14971, will see  
updated versions  
published.

**Harmonized  
Standards in the EU  
Changing, Updating**

The Medical Devices  
Directive has  
designated EN  
15223-1:2012 as the  
standard providing  
labeling symbols for all



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medical devices, and is currently the only labeling standard for medical devices listed in the EU official journal.

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