
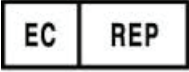





# Symbols Glossary Definition

## Symbols Derived from Standards

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Reference 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Reference 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	ISO 15223-1, Reference 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Reference 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Reference 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.



ISO 15223-1,  
Reference 5.1.6

Medical devices —  
Symbols to be used  
with medical device  
labels, labelling  
and information  
to be supplied  
— Part 1: General  
requirements.

Catalogue number

Indicates the  
manufacturer's  
catalogue number  
so that the medical  
device can be  
identified.



ISO 15223-1,  
Reference 5.2.7

Medical devices —  
Symbols to be used  
with medical device  
labels, labelling  
and information  
to be supplied  
— Part 1: General  
requirements.

Non-sterile

Indicates a medical  
device that has not  
been subjected  
to a sterilization  
process.



ISO 15223-1,  
Reference 5.2.8

Medical devices —  
Symbols to be used  
with medical device  
labels, labelling  
and information  
to be supplied  
— Part 1: General  
requirements.

Do not use  
if package is  
damaged

Indicates a medical  
device that should  
not be used if  
the package has  
been damaged or  
opened.



ISO 15223-1,  
Reference 5.3.2

Medical devices —  
Symbols to be used  
with medical device  
labels, labelling  
and information  
to be supplied  
— Part 1: General  
requirements.

Keep away from  
sunlight

Indicates a medical  
device that needs  
protection from  
light sources.



ISO 15223-1,  
Reference 5.4.2

Medical devices —  
Symbols to be used  
with medical device  
labels, labelling  
and information  
to be supplied  
— Part 1: General  
requirements

Do not reuse

Indicates a medical  
device that is  
intended for one  
use, or for use on  
a single patient  
during a single  
procedure.



ISO 15223-1,  
Reference 5.4.3

Medical devices —  
Symbols to be used  
with medical device  
labels, labelling  
and information  
to be supplied  
— Part 1: General  
requirements.

Consult instructions  
for use

Indicates the  
need for the user  
to consult the  
instructions for use.



ISO 15223-1,  
Reference 5.4.3

Medical devices —  
Symbols to be used  
with medical device  
labels, labelling  
and information  
to be supplied  
— Part 1: General  
requirements.

Consult electronic  
instructions for use

Indicates the  
need for the  
user to consult  
the electronic  
instructions for  
use (eIFU) at the  
specified website  
location.



ISO 15223-1,  
Reference 5.4.4

Medical devices —  
Symbols to be used  
with medical device  
labels, labelling  
and information  
to be supplied  
— Part 1: General  
requirements

Caution

Indicates the  
need for the user  
to consult the  
instructions for  
use for important  
cautionary  
information such  
as warnings and  
precautions that  
cannot, for a  
variety of reasons,  
be presented on  
the medical device  
itself.






ISO 15223-1,  
Reference 5.7.1

Medical devices —  
Symbols to be used  
with medical device  
labels, labelling  
and information  
to be supplied  
— Part 1: General  
requirements.

Patient number

Indicates a unique  
number associated  
with an individual  
patient.

# Symbols Not Derived from Standards

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
<b>Rx Only</b>	21 CFR 801.109	Labeling; Prescription devices	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive and Medical Device Regulation.	European conformity	European conformity (CE) mark with Notified Body identification number for Class Im, Ir, Is, IIa, IIb, III medical devices Notified Body No. 0086: BSI, United Kingdom
	MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive and Medical Device Regulation.	European conformity	European conformity (CE) mark with Notified Body identification number for Class Im, Ir, Is, IIa, IIb, III medical devices Notified Body No. 2797: BSI, Netherlands
	MDR 2017/745 Annex 1 23.2(q)	The requirements for indicating that a device is a medical device; Medical Device Regulation.	Medical device	Indicates that the device is a medical device.