# Symbols Glossary

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

| Symbol | Symbol Title | Description | Source/Reference |
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| EC REP | Authorized representative in the European community / European Union | Indicates the authorized representative in the European Community / European Union. | ISO 15223-1 #5.1.2 |
| UK RP | United Kingdom (UK) Responsible Person | Indicates the Responsible Person for placing the medical device on the UK market. | Nobel Biocare custom symbol |
| CH REP | Authorized representative in Switzerland | Indicates the authorized representative in Switzerland. | Swissmedic Information Sheet MU600_00_016e |
| STERILE EO | Sterilized using ethylene oxide | Indicates a medical device that has been sterilized using ethylene oxide. | ISO 15223-1 #5.2.3<br>ISO 7000-2501 |
| STERILE R | Sterilized using irradiation | Indicates a medical device that has been sterilized using irradiation. | ISO 15223-1 #5.2.4<br>ISO 7000-2502 |
| STERILE | Sterilized using steam or dry heat | Indicates a medical device that has been sterilized using steam or dry heat. | ISO 15223-1 #5.2.5<br>ISO 7000-2503 |
| LOT | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. | ISO 15223-1 #5.1.5<br>ISO 7000-2492 |
| REF | Catalogue number | Indicates the manufacturer's catalogue number so that the medical device can be identified. | ISO 15223-1 #5.1.6<br>ISO 7000-2493 |
| UDI | Unique device identifier | Indicates a carrier that contains unique device identifier information. | ISO 15223-1 #5.7.10 |
| SN | Serial number | Indicates the manufacturer's serial number so that a specific medical device can be identified. | ISO 15223-1 #5.1.7<br>ISO 7000-2498 |
| MD | Medical device | Indicates that the item is a medical device. | ISO 15223-1 #5.7.7 |
| MR | Magnetic resonance (MR) safe | Indicates a medical device that poses no known hazards resulting from exposure to any MR environment. | ASTM F2503 |
| MR | Magnetic resonance (MR) conditional | Indicates a medical device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields. | ASTM F2503 |
| | Caution | Indicates that caution is necessary when operating the device or close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. | ISO 15223-1 #5.4.4<br>ISO 7000-0434A |
| NON STERILE | Non-sterile | Indicates a medical device that has not been subjected to a sterilization process. | ISO 15223-1 #5.2.7<br>ISO 7000-2609 |
| | Contains hazardous substances | Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties. | ISO 15223-1 #5.4.10<br>ISO 7000-3723 |
| PHT DEHP | Contains or presence of DEHP phthalate | Indicates a medical device which is derived from or manufactured from materials containing phthalate: bis (2-ethylhexyl) phthalate (DEHP). | ISO 7000-2725<br>EN 15986 |

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|  | Contains or presence of phthalate | Indicates a medical device which is derived from or manufactured from materials containing phthalate. | ISO 7000-2725 |
|  | Contains or presence of natural rubber latex | Indicates the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device. | ISO 15223-1 #5.4.5<br>ISO 700-2725 |
|  | Contains biological material of animal origin | Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin. | ISO 15223-1 #5.4.8<br>ISO 7000-3699 |
|  | CE mark | Indicates that a medical device conforms with applicable requirements from European Union (EU) regulations. | EU Regulation 2017/745 (MDR) |
|  | CE mark with Notified Body number | Indicates that a medical device is certified by a Notified Body to conform with applicable requirements from EU regulations. | EU Regulation 2017/745 (MDR) |
|  | UKCA mark | Indicates a medical device which has been UK Conformity Assessed. | UK Medicines and Healthcare Products Regulatory Agency (MHRA) |
|  | UKCA mark with Approved Body number | Indicates a medical device which has been UK Conformity Assessed by a UK Approved Body. | UK Medicines and Healthcare Products Regulatory Agency (MHRA) |
|  | Consult instructions for use | Indicates the need for the user to consult the instructions for use. | ISO 15223-1 #5.4.3<br>ISO 7000-1641 |
|  symbol.glossary.nobelbiocare.com<br>ifu.nobelbiocare.com | Consult electronic instructions for use | Indicates the web address where electronic instructions for use and symbols glossary can be obtained by the user. | ISO 15223-1 #5.4.3<br>ISO 7000-1641 |
| **Rx only** | For prescription use only | Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner. | FDA Final rule, Use of symbols in labeling |
|  | Manufacturer | Indicates the medical device manufacturer. | ISO 15223-1 #5.1.1<br>ISO 7000-3082 |
|  | Date of manufacture | Indicates the date when the medical device was manufactured. | ISO 15223-1 #5.1.3<br>ISO 7000-2497 |
|  | Use-by date | Indicates the date after which the medical device is not to be used. | ISO 15223-1 #5.1.4<br>ISO 7000-2607 |
|  | Upper limit of temperature | Indicates the upper limit of temperature to which the medical device can be safely exposed. | ISO 15223-1 #5.3.6<br>ISO 7000-0533 |
|  | Temperature limit | Indicates the temperature limits to which the medical device can be safely exposed. | ISO 15223-1 #5.3.7<br>ISO 7000-0632 |
|  | Do not resterilize | Indicates a medical device that is not to be resterilized. | ISO 15223-1 #5.2.6<br>ISO 7000-2608 |
|  | Do not re-use | Indicates a medical device that is intended for one single use only. | ISO 15223-1 #5.4.2<br>ISO 7000-1051 |
|  | Non-pyrogenic | Indicates a medical device that is non-pyrogenic. | ISO 15223-1 #5.6.3<br>ISO 7000-2724 |
|  | Date | Indicates the date that information was entered or a medical procedure took place. | ISO 15223-1 #5.7.6<br>IEC 60417-5662 |
|  | Tooth number | Indicates the number / position of the tooth treated with the medical product. | Nobel Biocare custom symbol |
|  | Patient number | Indicates a unique number associated with an individual patient. | ISO 15223-1 #5.7.1<br>ISO 7000-2610 |
|  | Patient identification | Indicates the identification data of the patient. | ISO 15223-1 #5.7.3<br>IEC 60417-5662 |
|  | Health care centre or doctor | Indicates the address of the health care centre or doctor where medical information about the patient may be found. | ISO 15223-1 #5.7.5<br>ISO 7001 PI PF 044 |
|  | Patient information website | Indicates a website where a patient can obtain additional information on the medical product. | ISO 15223-1 #5.7.4<br>ISO 7000-3705 |
|  | EU Importer | Indicates the entity importing the medical device into the EU. | ISO 15223-1 #5.1.9<br>ISO 7000-3725 |

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|  | CH Importer | Indicates the entity importing the medical device into Switzerland. | ISO 15223-1 #5.1.9<br>ISO 7000-3725 |
|  | Double sterile barrier system | Indicates two sterile barrier systems. | ISO 15223-1 #5.2.12<br>ISO 7000-3704 |
|  | Single sterile barrier system | Indicates a single sterile barrier system. | ISO 15223-1 #5.2.11<br>ISO 7000-3707 |
|  | Single sterile barrier system with protective packaging inside | Indicates a single sterile barrier with protective packaging inside. | ISO 15223-1 #5.2.13<br>ISO 7000-3708 |
|  | Single sterile barrier system with protective packaging outside | Indicates a single sterile barrier with protective packaging outside. | ISO 15223-1 #5.2.14<br>ISO 7000-3709 |
|  | Do not use if package is damaged and consult instructions for use | Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information. | ISO 15223-1 #5.2.8<br>ISO 7000-2606 |
|  | Keep away from sunlight | Indicates a medical device that needs protection from light sources. | ISO 15223-1 #5.3.2<br>ISO 7000-0624 |
|  | Keep dry | Indicates a medical device that needs to be protected from moisture. | ISO 15223-1 #5.3.4<br>ISO 7000-0626 |