

Medical Devices Packaging And Labeling Symbols

A candle loses nothing by lighting another candle.



Ehsan Abbasi

CompuHyper GlobalMed®

Ultra Implantable™

Fictitious Medical Device
2.25 mm x 8 mm

CAT 123456

LOT 12345678



USE BY:
2020-01-01

QTY: 1 EA



SINGLE USE



DO NOT USE
IF PACKAGE
IS DAMAGED



UPPER
LIMIT OF
TEMPERATURE



KEEP DRY



Manufacturer

CompuHyperGlobalMed
123 Technology Dr
Somewhere, XX 00000

800.555.1234 (USA)
555.555.1234 (All Others)
www.chgm.com

MedDevFront UK
Somewhereshire
XX12 3XX UK

www.mdf.co.uk



12356712686021987231(99)156046712987

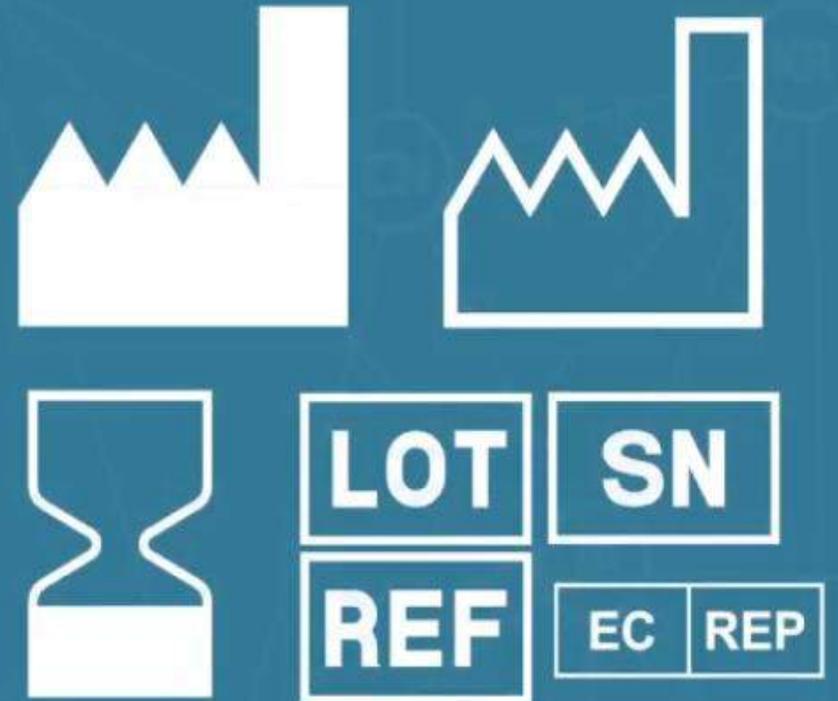
COMMON SEVEN SYMBOLS CATEGORIES

- Manufacture
- Storage
- Safe Use
- Sterility
- IVD Specific
- Transfusion/Infusion
- Others

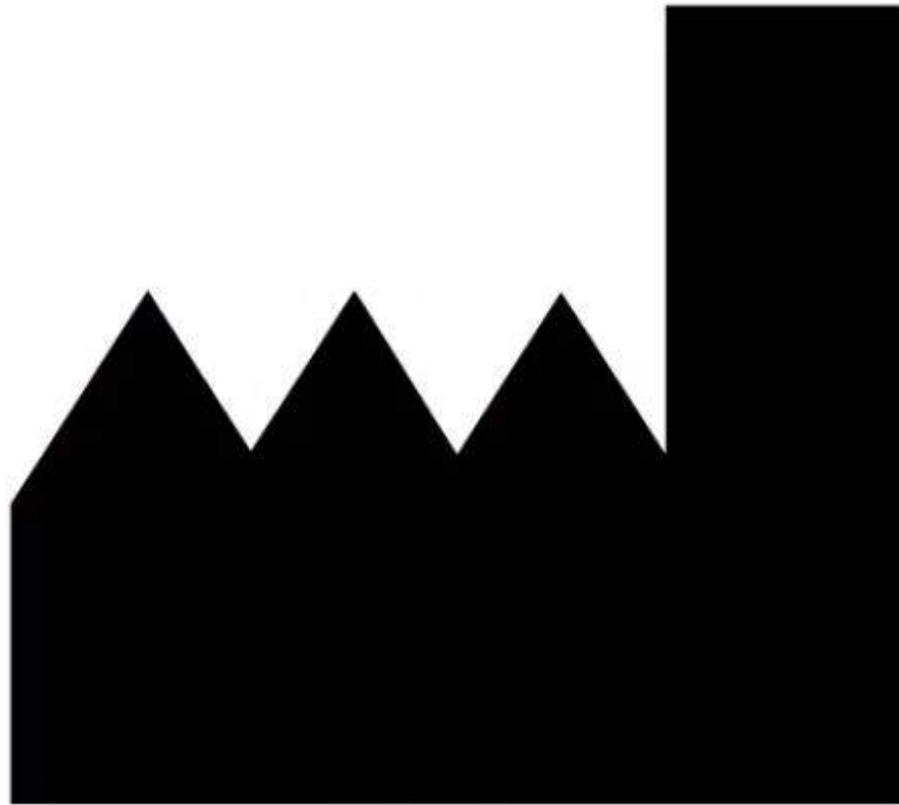


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Manufacturer Symbols



Manufacturer



Description: Indicates the device manufacturer.

Notes:

- Used in the EU.
- Includes the name and address of the device manufacturer.
- Information is located adjacent to the symbol.

Authorized Representative



Description:

Indicates the Authorized Representative in the European Community.

Notes:

- Applies to manufacturers distributing in the EU.
- This symbol is accompanied by the name and address of the authorized representative.

Date of Manufacture



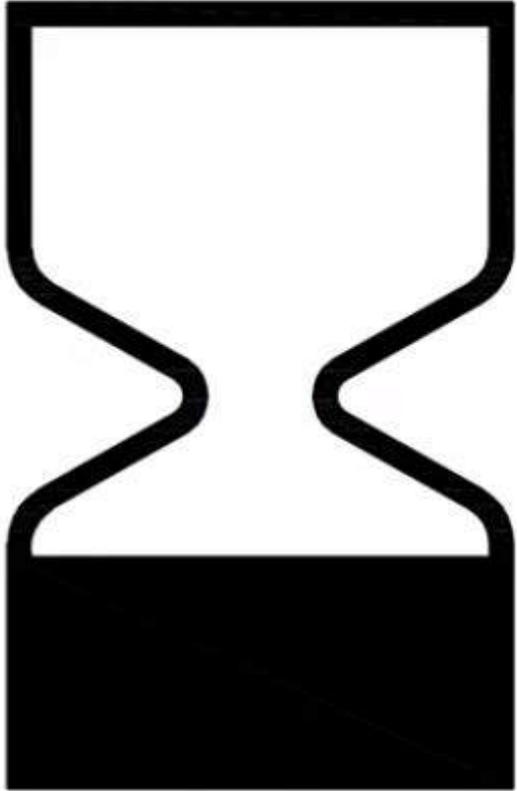
Description:

Indicates the date when the medical device was manufactured.

Notes:

- It is accompanied by the manufacturing date which is placed adjacent to the symbol.
- Date is expressed as four digits for the year and, where appropriate, two digits for the month and two digits for the day (e.g. 2015-10-30).

Use-by Date



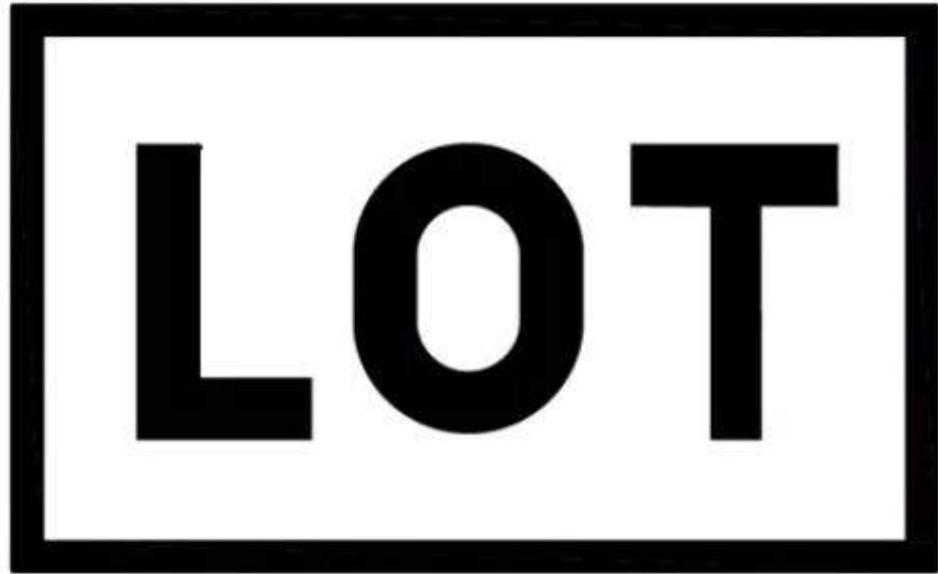
Description:

Indicates the date after which the medical device is not to be used.

Notes:

- It is accompanied by an expiration date.
- The date is expressed as four digits for the year and, where appropriate, two digits for the month and two digits for the day (e.g. 2015-10-30).
- The date is located adjacent to the symbol.

Batch Code



Description:

Indicates the manufacturer's batch code so that the batch or lot can be identified.

Notes:

- This symbol is accompanied by the manufacturer's batch code.
- The batch code is adjacent to the symbol.

Catalogue Number



REF

Description:

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

Notes:

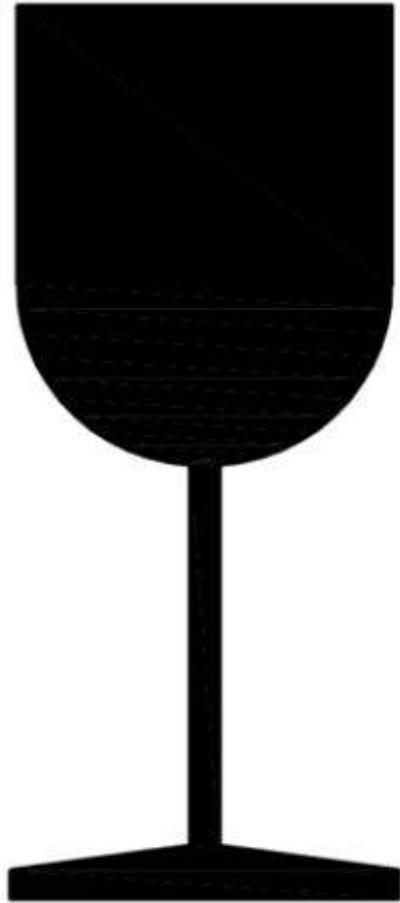
- Placed adjacent to the symbol.

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Storage Symbols



Fragile, Handle with Care



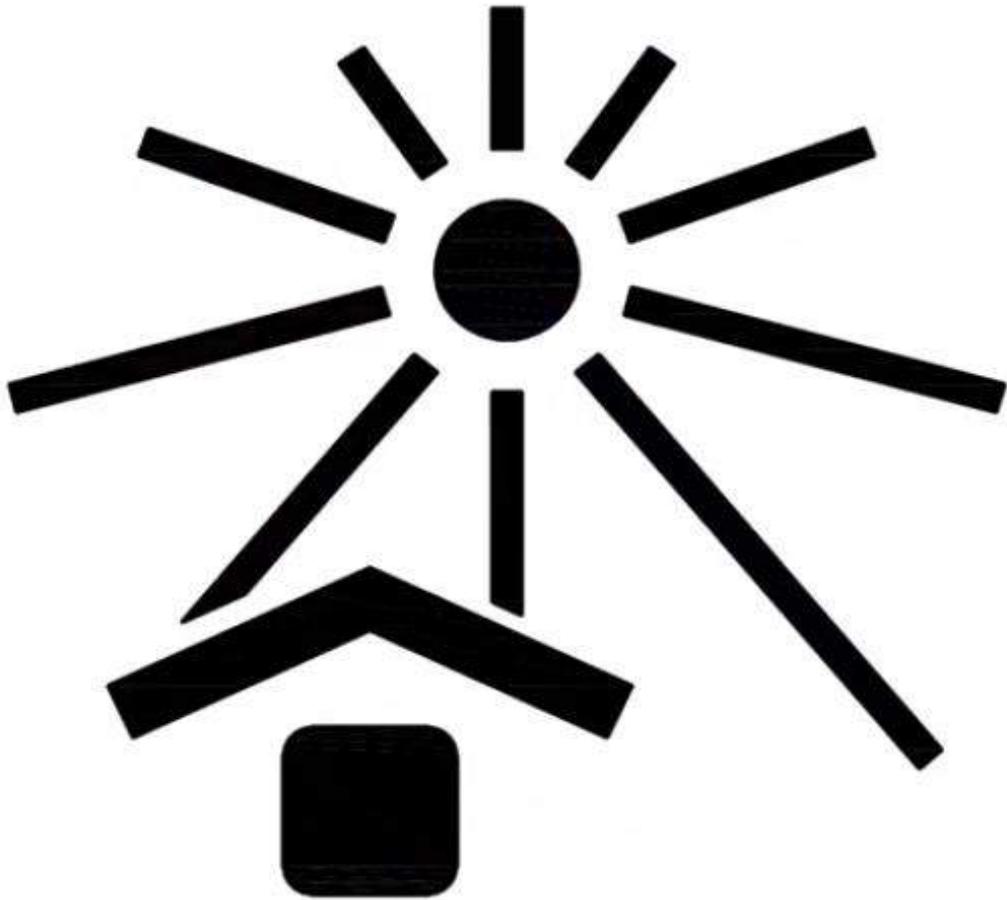
Description:

Indicates a medical device that can be broken or damaged if not handled carefully.

Notes:

- No special requirements.

Keep Away from Sunlight



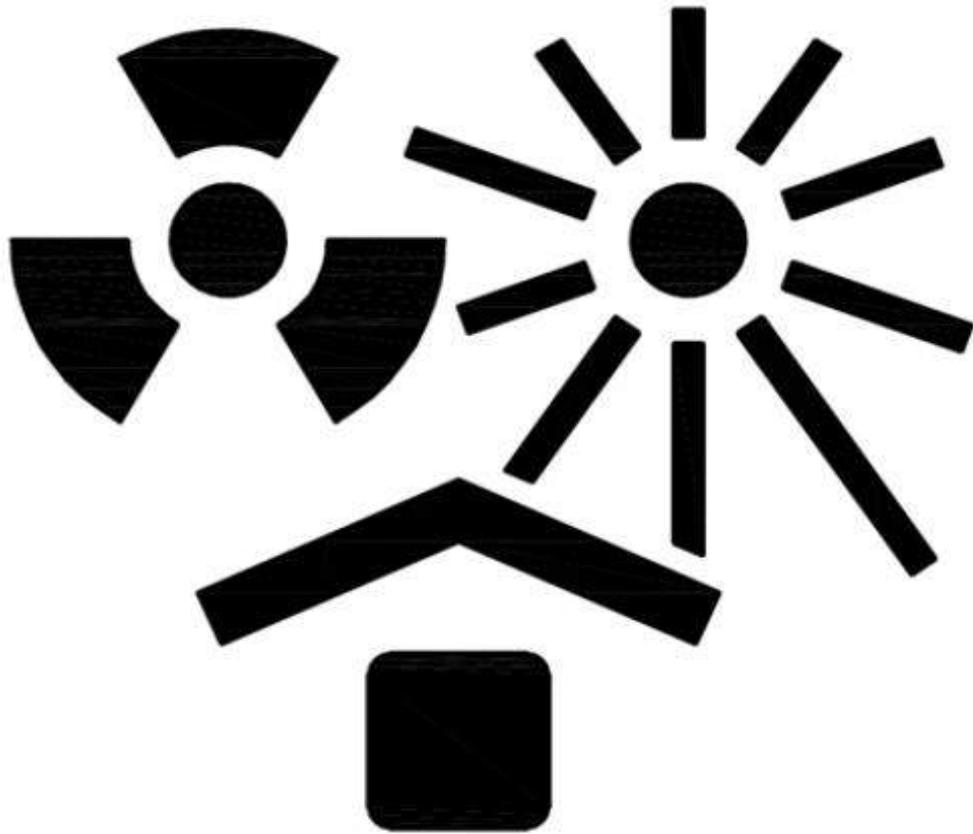
Description:

Indicates a medical device that needs protection from light sources.

Notes:

- This symbol can also mean "Keep away from heat."

Protect from Heat and Radioactive Sources



Description:

Indicates a medical device that needs protection from heat and radioactive sources.

Notes:

- This symbol can also mean "Keep away from sunlight and radioactive sources."

Keep Dry



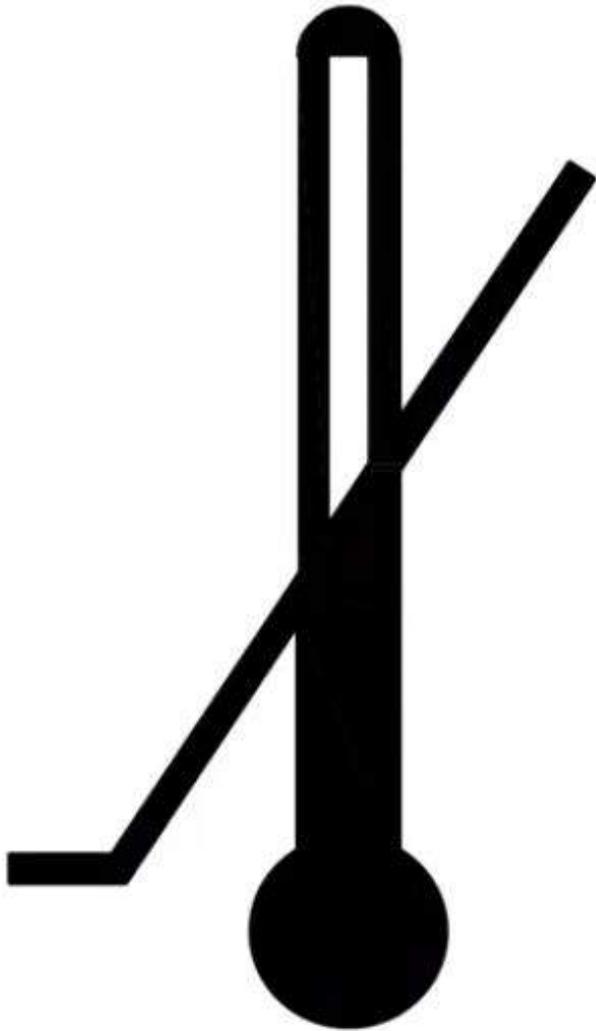
Description:

Indicates a medical device that needs to be protected from moisture.

Notes:

- This symbol can also mean "Keep away from rain."

Lower Limit of Temperature



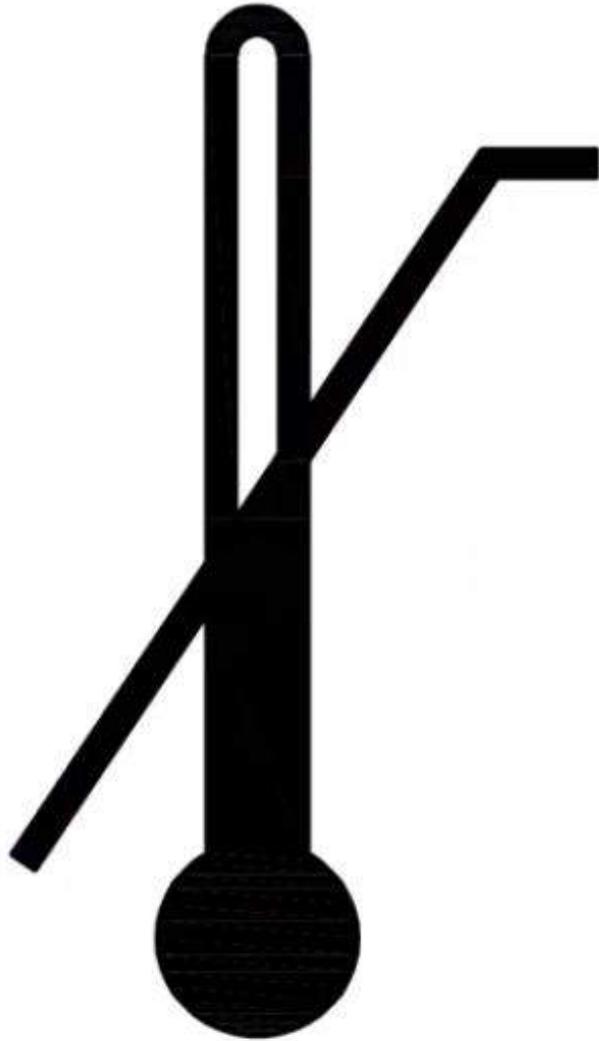
Description:

Indicates the lower limit of temperature to which the medical device can be safely exposed.

Notes:

- The lower limit of temperature is indicated adjacent to the lower horizontal line.

Upper Limit of Temperature



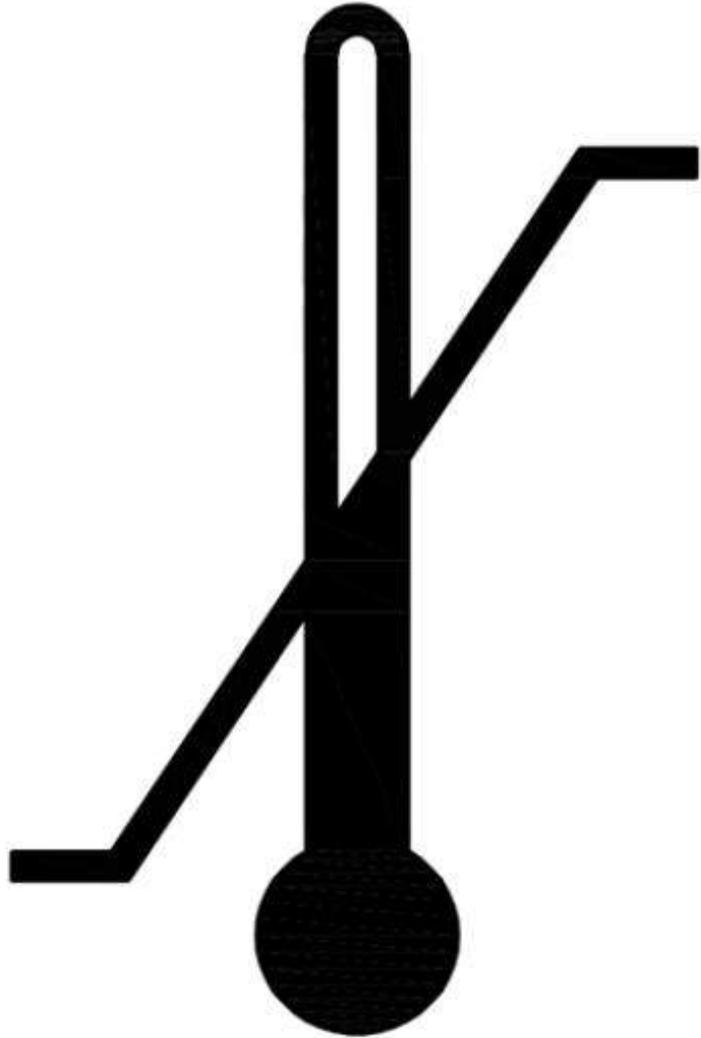
Description:

Indicates the upper limit of temperature to which the medical device can be safely exposed.

Notes:

- The lower limit of temperature is indicated adjacent to the upper horizontal line.

Temperature Limit



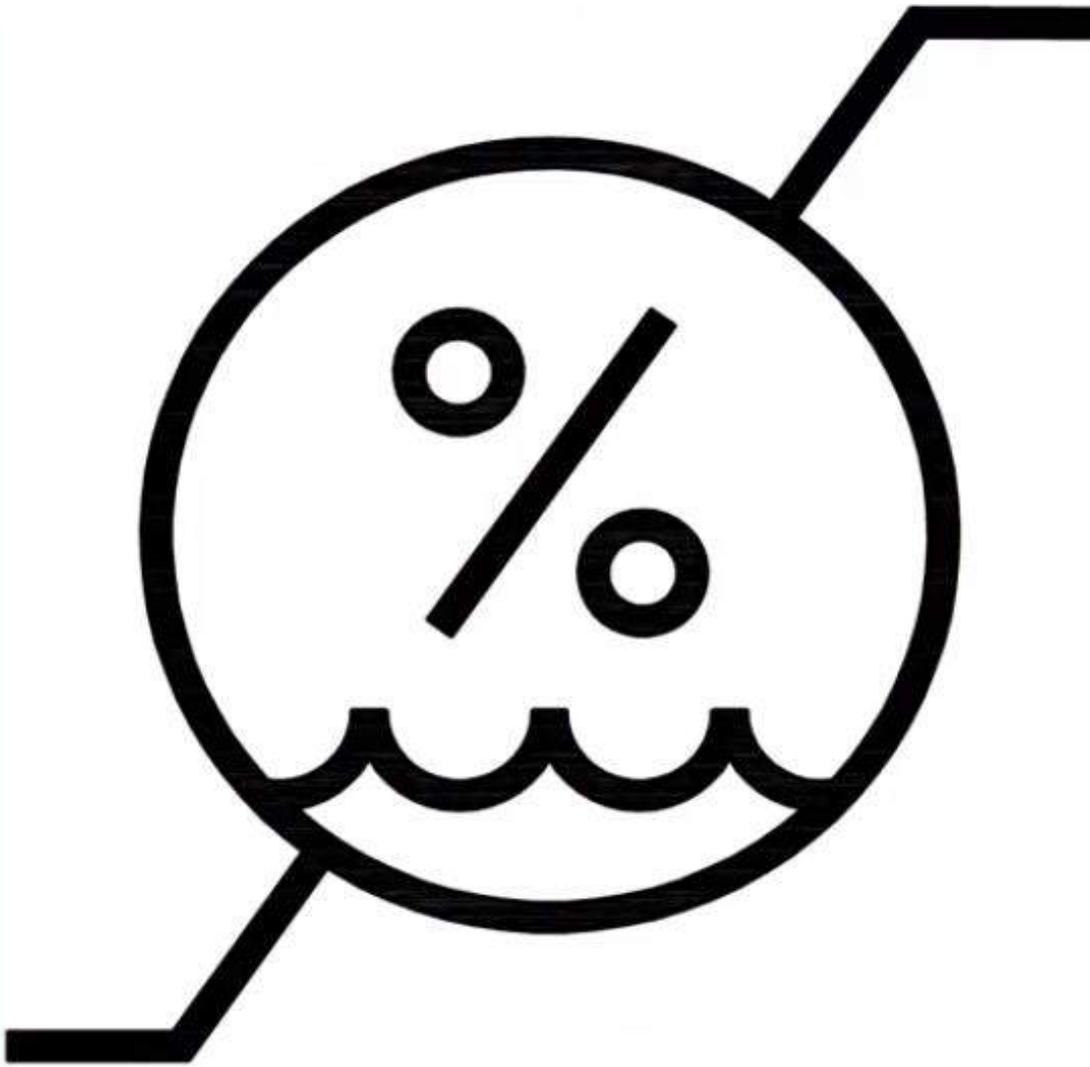
Description:

Indicates the temperature limits to which the medical device can be safely exposed.

Notes:

- The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.

Humidity Limitation



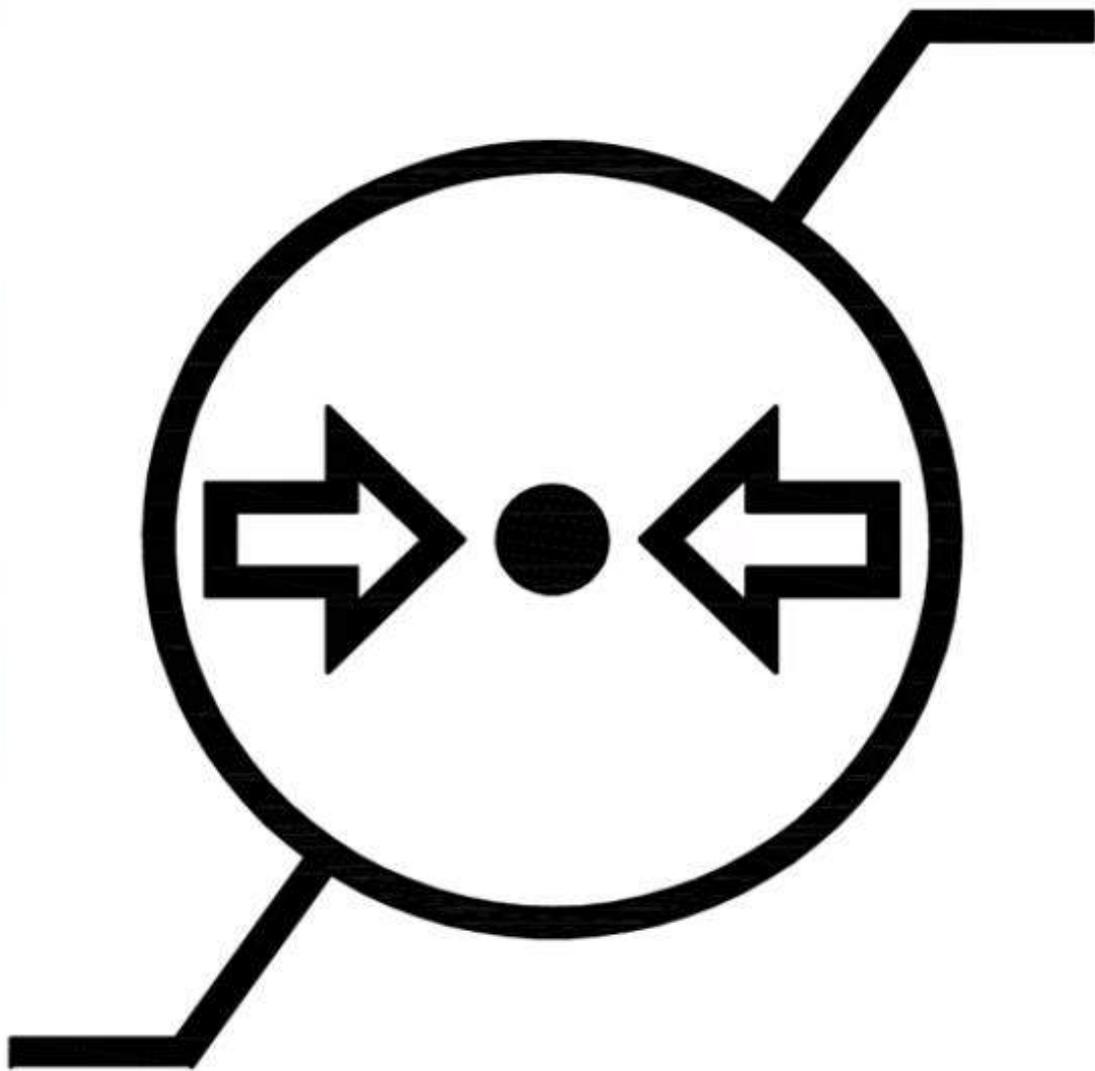
Description:

Indicates the range of humidity to which the medical device can be safely exposed.

Notes:

- The humidity limitation is indicated adjacent to the upper and lower horizontal lines.

Atmospheric Pressure Limitation



Description:

Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Notes:

- The atmospheric pressure limitations are indicated adjacent to the upper and lower horizontal lines.

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Safe Use Symbols



Biological Risks



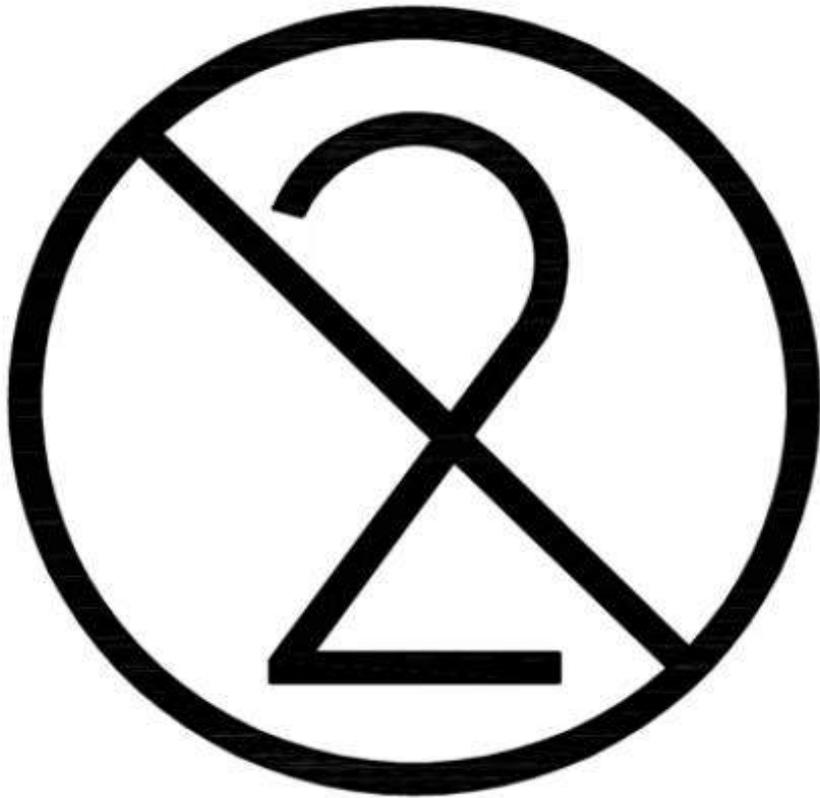
Description:

Indicates that there are potential biological risks associated with the medical device.

Notes:

- Do not confuse this sign with the "Biohazard" sign.

Do Not Reuse



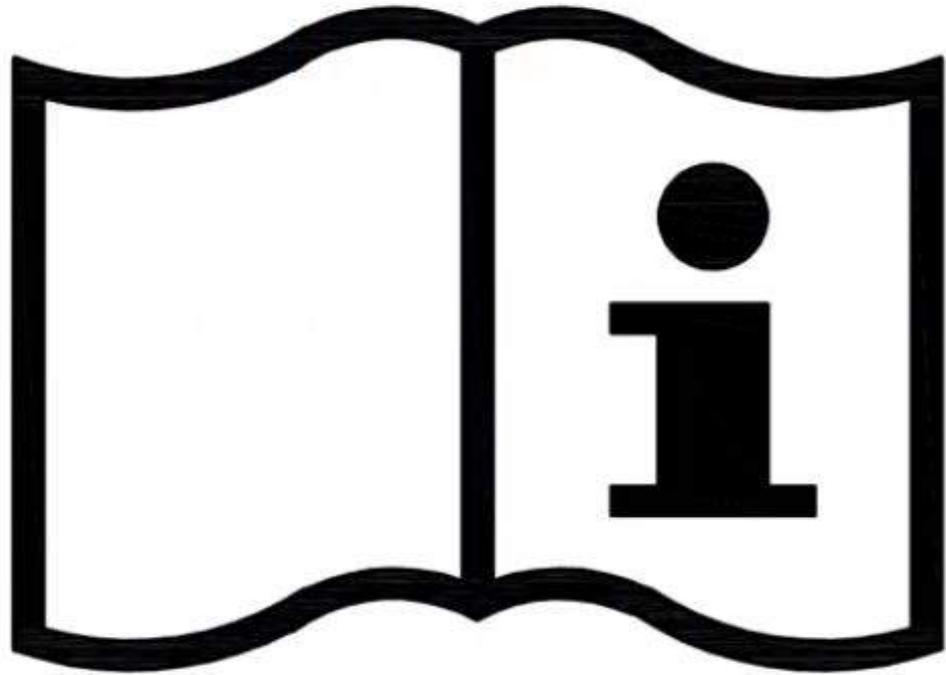
Description:

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

Notes:

- Also referred to as “single use” or “use only once.”

Consult Instructions for Use



Description:

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

Notes:

- Also referred to as “Consult operating instructions.”

Caution



Description:

Indicates the need for the user to consult the IFU for important cautionary information.

Notes:

- This symbol should be used to highlight that there are specific warnings or precautions associated with the medical device, which are not otherwise found on the label.

Contains or Presence of Natural Rubber Latex



Description:

Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.

Notes:

- This symbol is intended to warn those people who may have allergic reactions to certain proteins in latex.

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Sterile Symbols



Sterile



STERILE

Description:

Indicates a medical device that has been subjected to a sterilization process.

Notes:

- In Europe, this symbol is restricted to use on terminally sterilized medical devices.

Sterilized using aseptic processing techniques



Description:

Indicates a medical device that has been manufactured using accepted aseptic techniques.

Notes:

- No special requirements.

Sterilized Using Ethylene Oxide



Description:

Indicates a medical device that has been sterilized using ethylene oxide.

Notes:

- In Europe, this symbol is restricted to use on terminally sterilized medical devices.

Sterilized Using Irradiation



Description:

Indicates a medical device that has been sterilized using irradiation.

Notes:

- In Europe, this symbol is restricted to use on terminally sterilized medical devices.

Sterilized Using Steam or Dry Heat



Description:

Indicates a medical device that has been sterilized using steam or dry heat.

Notes:

- In Europe, this symbol is restricted to use on terminally sterilized medical devices.

Do Not Resterilize



Description:

Indicates a medical device that is not to be resterilized.

Notes:

- No special requirements.

Non-sterile



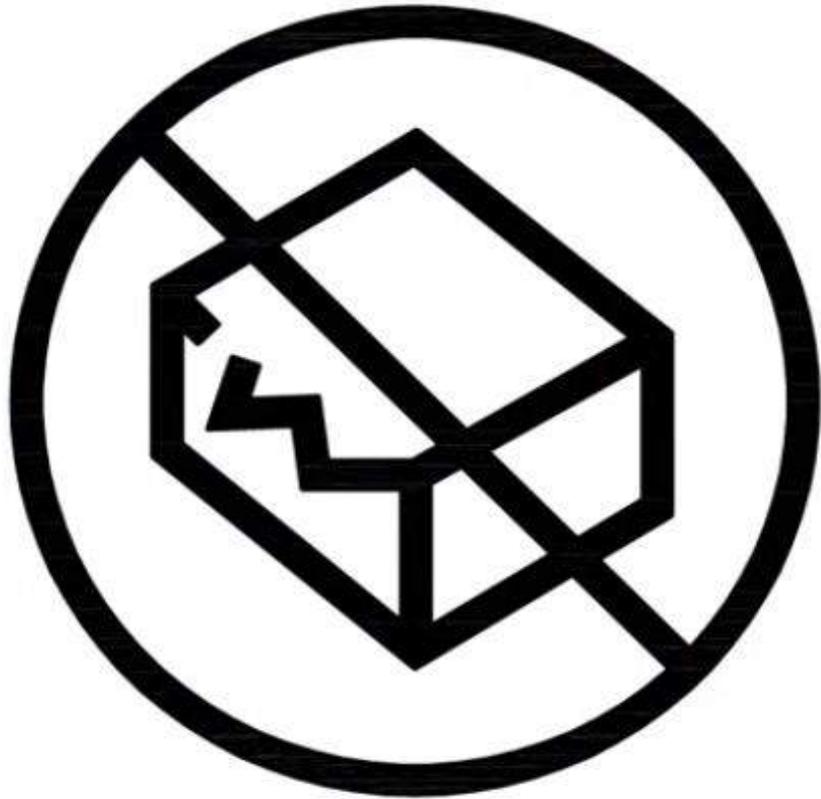
Description:

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

Notes:

- This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.

Do Not Use if Package is Damaged



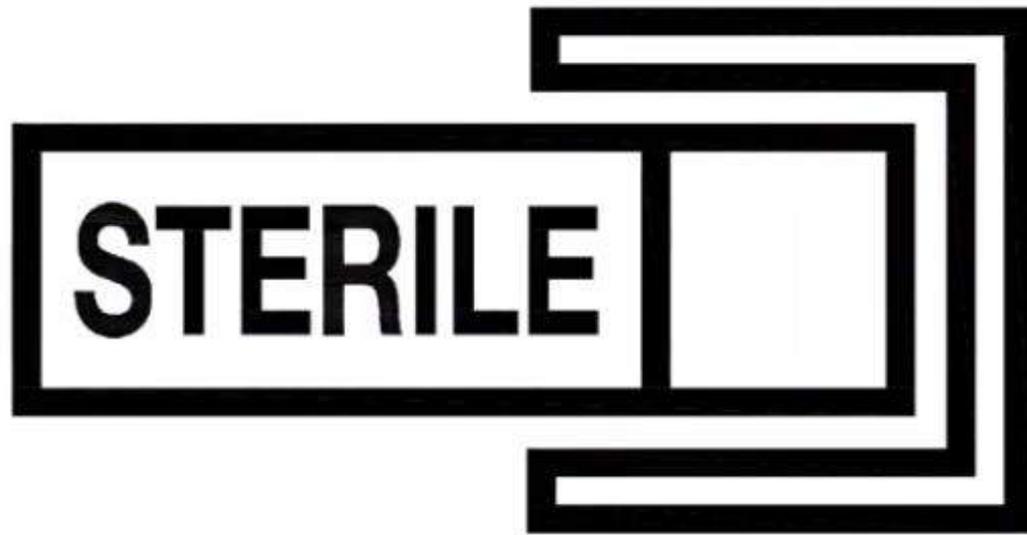
Description:

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

Notes:

- This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised."

Sterile Fluid Path



Description:

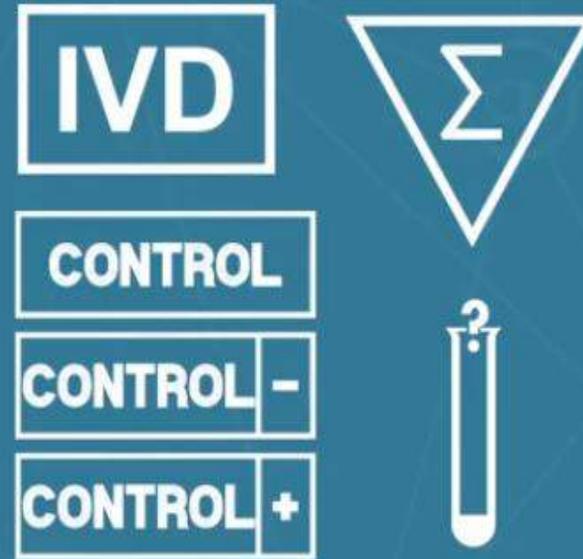
Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.

Notes:

- The method of sterilization shall be indicated in the empty box, as appropriate.
- The part of the medical device that is sterile shall be identified in the information supplied by the manufacturer.

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IVD Symbols



In Vitro Diagnostic Medical Device



Description:

Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.

Notes:

- This symbol should only be used to identify in vitro diagnostic medical devices and not to specify that the medical device is for “in vitro use.”

Control



CONTROL

Description:

Indicates a control material that is intended to verify the performance characteristics of another medical device.

Notes:

- No special requirements.

Negative Control



Description:

Indicates a control material that is intended to verify the results in the expected negative range.

Notes:

- No special requirements.

Positive Control



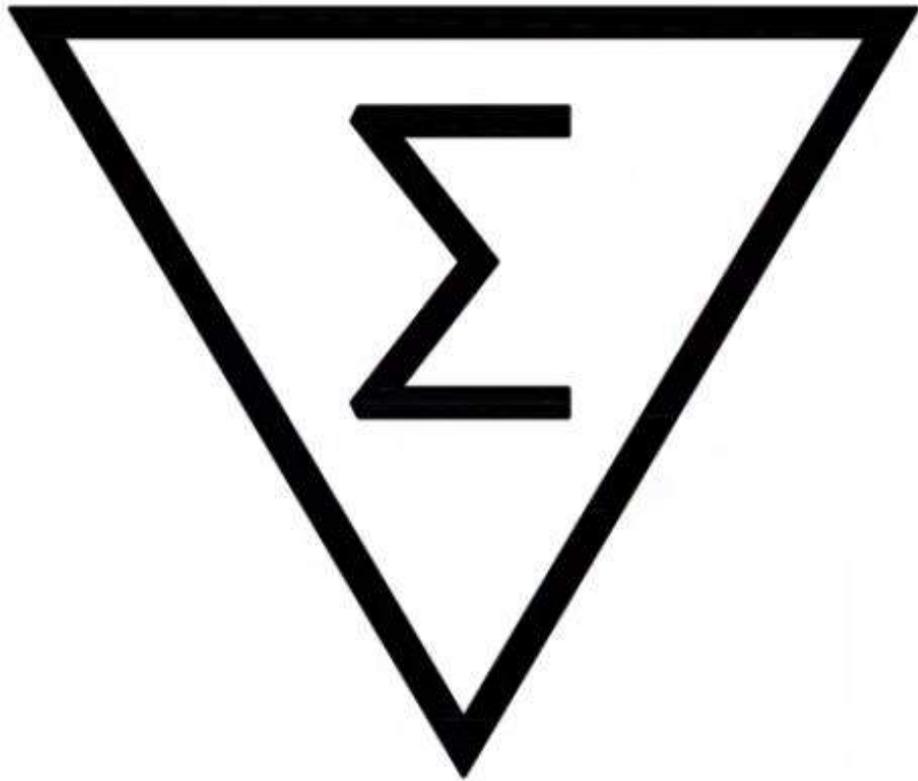
Description:

Indicates a control material that is intended to verify the results in the expected positive range.

Notes:

- No special requirements.

Contains Sufficient for <n> Tests



Description:

Indicates the total number of IVD tests that can be performed with the IVD kit reagents.

Notes:

- The number of tests that can be performed with the kit reagents appears adjacent to the symbol.
- The relative size of the symbol and the number of tests performed can vary.

For IVD Performance Evaluation Only



Description:

Indicates an IVD device that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use.

Notes:

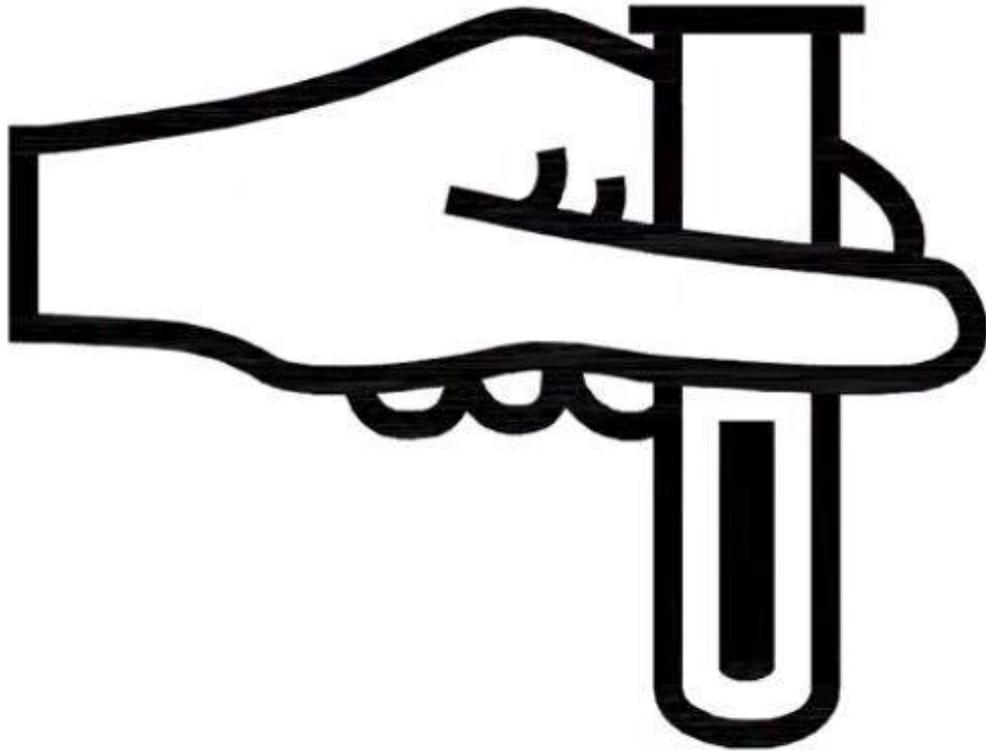
- Also referred to as “IVD for investigational use only.”
- A medical device that is for IVD performance evaluation only is not intended to be used for an in vitro diagnostic examination for medical purposes.
- This symbol cannot appear on a label that already has the IVD symbol.

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Transfusion/Infusion Symbols



Sampling Site



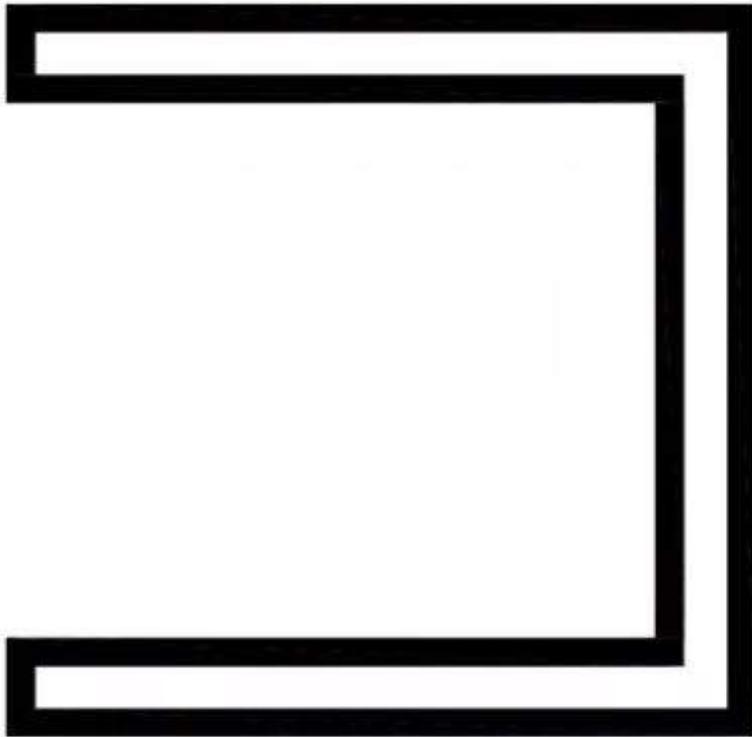
Description:

Indicates a medical device or blood processing application that includes a system dedicated to the collection of samples of a given substance stored in the medical device or blood container.

Notes:

- This is not to be associated with a site on a patient where samples are taken.

Fluid Path



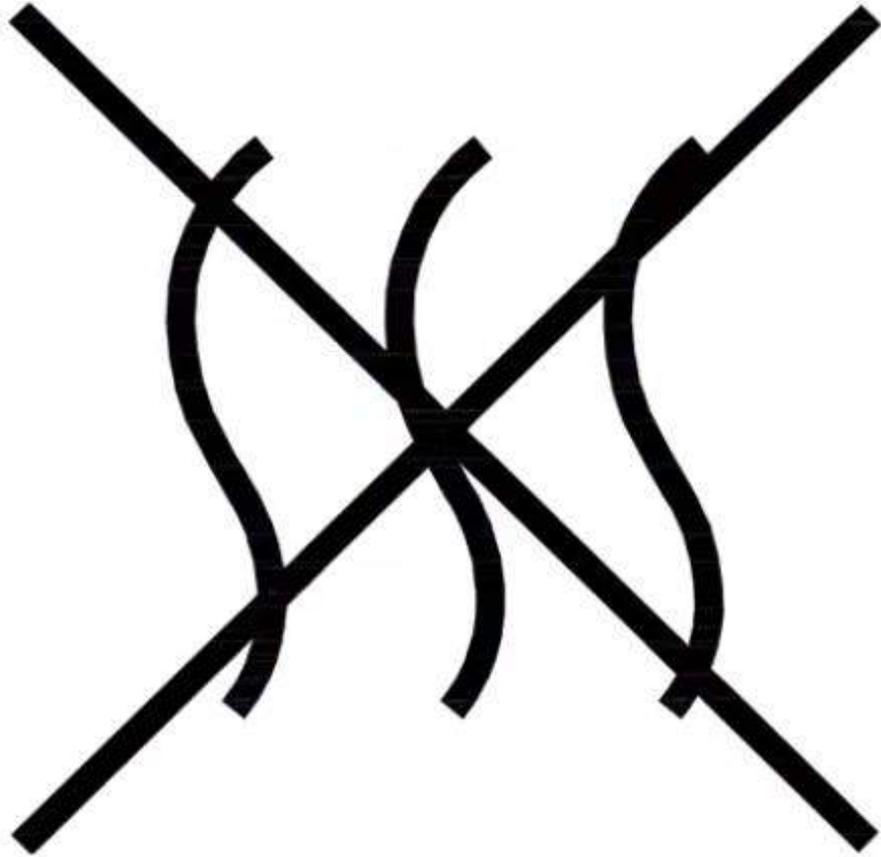
Description:

Indicates the presence of a fluid path.

Notes:

- No special requirements.

Non-pyrogenic



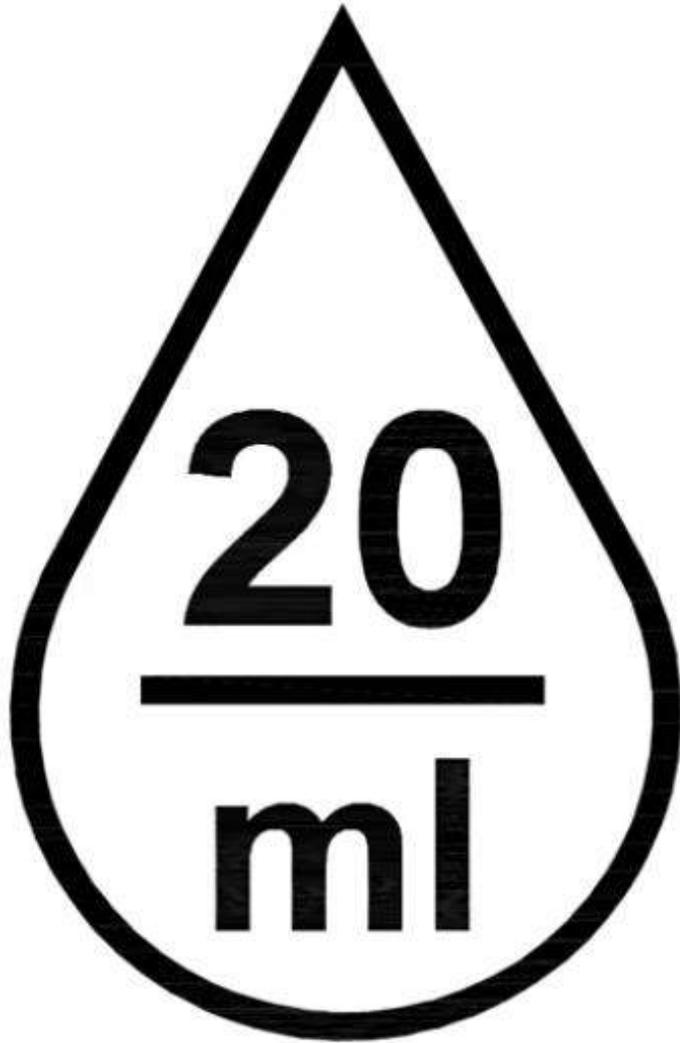
Description:

Indicates a medical device that is non-pyrogenic.

Notes:

- No special requirements.

Drops Per Milliliter



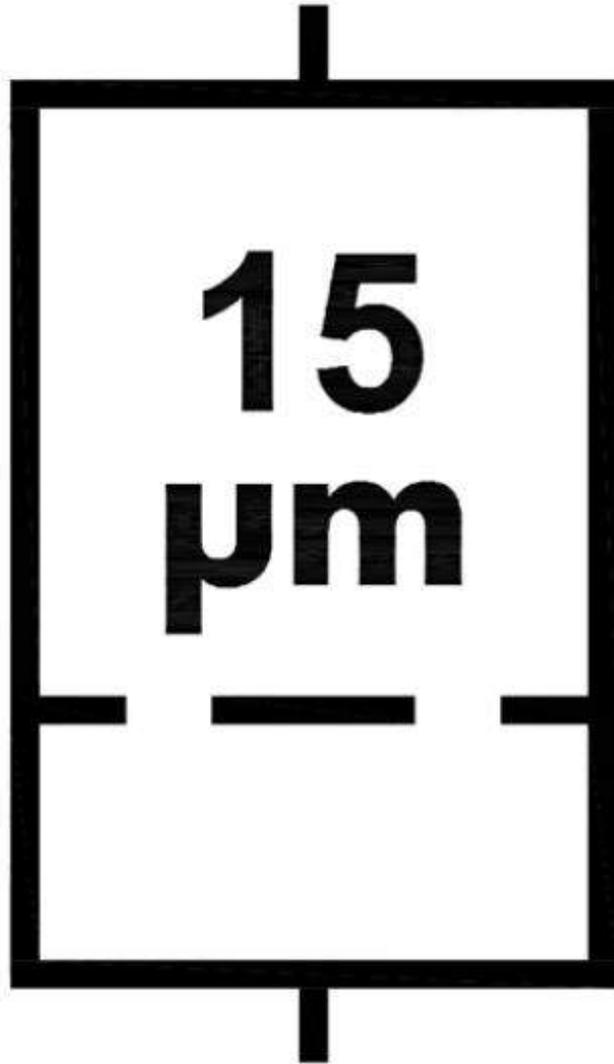
Description:

Indicates the number of drops per millilitre.

Notes:

- The number of drops per millilitre is specified; 20 is shown as an example and should be replaced by the appropriate number of drops per millilitre.

Liquid Filter with Pore Size



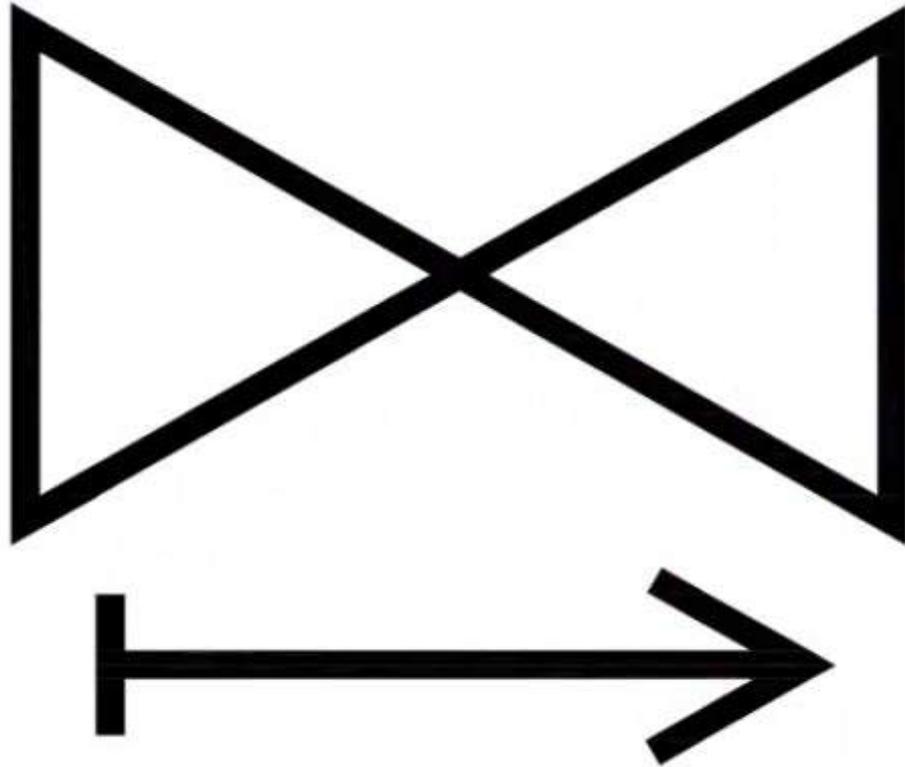
Description:

Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size.

Notes:

- The nominal pore size of the filter is specified; 15 is shown as an example and should be replaced by the appropriate pore size.

One-way Valve



Description:

Indicates a medical device with a valve that allows flow in only one direction.

Notes:

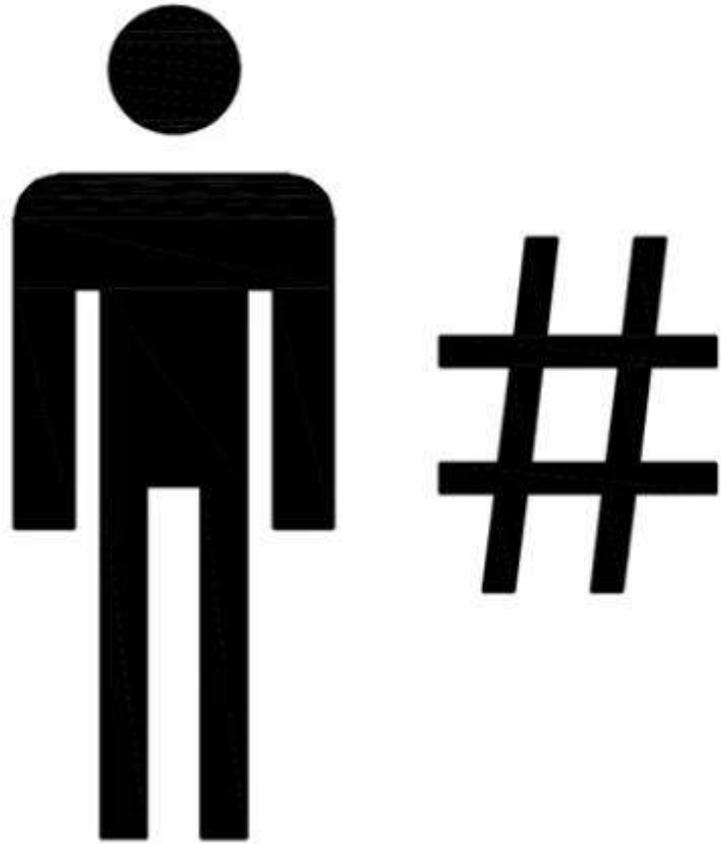
- It is important for users to know that the flow is only possible in one direction and cannot be reversed.

7

Other Symbols



Patient Number



Description:

Indicates a unique number associated with an individual patient.

Notes:

- No special requirements.

