

# Use of Symbols to Indicate Compliance with the MDR

November 2021

Version 3.0 (replaces version 2.0 of December 2019)

The Medical Devices Regulation 2017/745/EU ('MDR') has new requirements that ask for various kinds of information to be indicated on the label of medical devices. Originally, the present guidance was developed to support compliance with labelling requirements of the MDR in a harmonised manner before the publication of *ISO 15223-1: 2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*, which has now been published (July 2021). Therefore, the present guidance has been updated to align with the new ISO 15223-1:2021.

For information on use of symbols mentioned in the present document ISO 15223-1: 2021 should be consulted.

The present guidance covers the following:

1. Medical device
2. Contains human blood or plasma derivatives
3. Contains a medicinal substance
4. Contains hazardous substances
5. Contains biological material of human origin
6. Contains biological material of animal origin
7. Sterilized using vaporized hydrogen peroxide
8. Translation
9. Repackaging
10. Single Patient Multiple use<sup>11</sup>. Single sterile barrier system
12. Double sterile barrier system
13. Single sterile barrier system with protective packaging inside
14. Single sterile barrier system with protective packaging outside
15. Importer
16. Distributor
17. Unique Device Identifier
18. Contains nano materials

*Additionally, in Annex II of the present guidance MedTech Europe recommends **symbols to be used with patient implant card.***

### Disclaimer

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MedTech Europe has been given a permission by the Belgian standardisation body NBN (*Bureau de normalisation*) to use in this document symbols included in ISO 15223-1(2021) Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements.

Please note that this document is not a standard or normative document and all official standards referenced in this publication are available at NBN.

MedTech Europe reserves the right to change or amend the document at any time without notice.

## Why symbols?

There are 24 official languages in Europe, which creates a necessity to translate the information provided on the labels into multiple languages, depending on where the device is made available. This requirement can be dealt with by using symbols. The use of symbols on the label as an alternative to written language is permitted in the MDR regulation: Annex 1, chapter III, 23.1. h). Symbols are efficient, cost saving and internationally understood concepts to convey the required information to the user of a medical device.

## MDR legislative references

Annex 1, chapter III, paragraph 23.2 ‘Information on the label’ outlines what must be included on the label and serves as the legislative reference for the following symbols:

The symbols below can either be found on the [ISO Online Browsing Platform \(https://www.iso.org/obp\)](https://www.iso.org/obp) or in ISO 15223-1:2021. If a symbol is registered in ISO 7000 its numerical reference is included next to the symbol title. Otherwise, symbols not registered in ISO 7000 are found only within ISO 15223-1:2021.

**1. Medical device**

MDR, Annex 1, 23.2, q.

**2. Contains human blood or plasma derivatives (3701)**

MDR, Annex 1, 23.2, e.

**3. Contains a medicinal substance (3702)**

MDR, Annex 1, 23.2, e

**4. Contains hazardous substances (3723)**

MDR Annex 1, 23.2.(f)

**Note:**

*For additional guidance on how to provide information (e.g. in the Instructions for Use) on CMR/ED substances present in the medical device, materials or parts thereof, please consult MedTech Europe's guidance on 'MDR Requirements on Hazardous Substances' (section on labelling). This guidance is internal and available to MedTech Europe members only.*

**5. Contains biological material of human origin (3700)**

MDR, Annex 1, 23.2, e.

This symbol indicates that the medical device to which it is affixed contains tissues or cells, or their derivatives, of human origin

**6. Contains biological material of animal origin (3699)**

MDR, Annex 1, 23.2, e.

This symbol indicates that the medical device to which it is affixed contains tissues or cells, or their derivatives, of animal origin.

**7. Sterilized using vaporized hydrogen peroxide**

MDR, Annex I, 23.2, l. (method of sterilization)

**8. Translation (3728) & 9. Repackaging (3727)**

- MDR Art. 16, point 3 requires these activities to be mentioned on the device/ its packaging or accompanying document: *“A distributor or importer that carries out any of the activities mentioned in points (a – includes translation) and (b - includes repackaging) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.”*

These symbols have been developed for use by such entities to facilitate their compliance with the MDR

**10. Single Patient – Multiple use (3706)**

- Medtech Europe recommends use of the present symbol for ‘Single patient - multiple use’ meaning. This symbol is part of the ISO 152231 standard and a part of the ISO 7000 database. Its use is supported by references in the ISO and IMDRF documents.
- References made in ISO 20417: 2021 Medical devices — Information to be supplied by the manufacturer and IMDRF 2019“Principles of Labelling for Medical Devices and IVD Medical Devices”, Art. 5.2.18: ‘

#### **11. Single sterile barrier system (3707)**

#### **12. Double sterile barrier system (3704)**

#### **13. Single sterile barrier system with protective packaging inside (3708)**

#### **14. Single sterile barrier system with protective packaging outside (3709)**

MDR Annex I GSPR 23.3. ‘*information on the packaging which maintains the sterile condition of a device* (‘sterile packaging’) and concretely point a) of that section: ‘*an indication permitting the sterile packaging to be recognised as such*’ form the requirement for which these four symbols have been developed.

#### **15. Importer (3725) & 16. Distributor (3724)**

Importer and Distributor have new obligations under the MDR, which include for instance indication on the label of their activities with regards to repackaging and translation (MDR Art.16). These symbols were developed to facilitate MDR compliance.

#### **17. Unique Device Identifier**

MDR 2017/745 – Annex VI, Part C The UDI System, 4. UDI Carrier, 4.5. ‘*When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable.*’

#### **18. Contains nano materials (3703)**

MDR pays increased attention to nano materials (for instance Annex I GSPR, chapter II, Art.10.6) and, while not formally requesting that specific information regarding nano materials needs to be indicated on the label, the creation of this symbol is considered useful.

### **Symbol validation & process**

MedTech Europe performed a validation of symbols 1,2,4-6,8-10 above according to the ISO (International Standardisation Organisation) 15223-2 process (*ISO 15223-2:2010-01 Medical Devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 2: Symbol development, selection and validation*). The validation was run in five languages in multiple geographies and included patients and healthcare providers. MedTech Europe members performed validation of the remaining new symbols in line with the above-mentioned ISO 15223-2 process.

All symbols are scalable and recognizable at 5 mm height (the same minimum height required for the CE Mark). They will ensure that medical devices comply with the MDR in an efficient manner and will clearly communicate the relevant information to end users such as healthcare professionals and patients.

Based on the validation results and the ISO TC 210 WG 03 feedback, in May 2019 MedTech Europe presented the symbols in Annex I of this document with descriptions in all 24 EU official languages, which was followed in December 2019 with an updated version of this guidance (including minor changes to the symbols – listed in Annex III).

## A note on the use of symbols

***In the European Union, these symbols must be described in the Instructions for Use in line with the MDR 23.1. h) until they are published in a harmonised European standard. Note that jurisdictions outside of the EU may have different requirements regarding the ‘Information to be Supplied by the Manufacturer’.***

When using the template provided in the annex:


- If some of the symbols are not needed for your particular needs, you can drop all or some of the symbols from the list, but **MedTech Europe strongly recommends you to keep always the same order** as shown on the attached listing. Always using the same order by the manufacturer will speed up user recognition and acceptance of the symbols and their meaning.
- Please make sure you **always use the same titles as given in ISO 7000 or ISO 15223-1:2021** (to avoid any confusion amongst users).

## Annex I


### Symbol designs, titles, and translations


All symbols included in this document are to be found in ISO 15223-1 (2021) *2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements.*

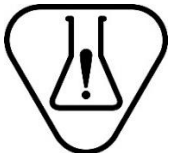
	
en	<b>Medical Device</b>
de	<i>Medizinprodukt</i>
fr	<i>Dispositif médical</i>
bg	<i>Медицинско изделие</i>
cs	<i>Zdravotnický prostředek</i>
da	<i>Medicinsk udstyr</i>
el	<i>Ιατροτεχνολογικό προϊόν</i>
es	<i>Producto sanitario</i>
et	<i>Meditsiiniseade</i>
fi	<i>Lääkinnällinen laite</i>
hr	<i>Medicinski proizvod</i>
hu	<i>Orvostechnikai eszköz</i>
it	<i>Dispositivo medico</i>
lt	<i>Medicinos priemonė</i>
lv	<i>Medicīniska ierīce</i>
nl	<i>Medisch hulpmiddel</i>
no	<i>Medisinsk utstyr</i>
pl	<i>Wyrób medyczny</i>


	
en	<b>Contains human blood or plasma derivatives</b>
de	<i>Enthält menschliches Blut oder Plasmaderivate</i>
fr	<i>Contient du sang humain ou des dérivés du plasma</i>
bg	<i>Съдържа човешки кръвни или плазмени производни</i>
cs	<i>Obsahuje lidskou krev nebo deriváty plazmy</i>
da	<i>Indeholder humant blod- eller plasmaderivat</i>
el	<i>Περιέχει ανθρώπινο αίμα ή παράγωγα πλάσματος</i>
es	<i>Contiene sangre humana o derivados de plasma</i>
et	<i>Sisaldab inimese vere või plasma derivaate</i>
fi	<i>Sisältää ihmisen veren tai plasman johdannaisia</i>
hr	<i>Sadrži ljudsku krv ili derivate plazme</i>
hu	<i>Emberi vért vagy plazma-származékokat tartalmaz</i>
it	<i>Contiene sangue umano o derivati del plasma</i>
lt	<i>Sudėtyje yra žmogaus kraujo arba plazmos preparatų</i>
lv	<i>Satur cilvēka asinis vai plazmas atvasinājumus</i>
nl	<i>Bevat menselijk bloed of plasmaderivaten</i>
no	<i>Inneholder humant blod eller plasmaderivater</i>
pl	<i>Zawiera ludzką krew lub pochodne osocza</i>

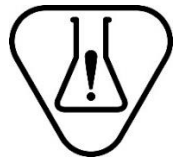
	
pt	<i>Dispositivo médico</i>
ro	<i>Dispozitiv medical</i>
ru	<i>Медицинское изделие</i>
sk	<i>Zdravotnícka pomôcka</i>
sl	<i>Medicinski pripomoček</i>
sr	<i>Медицинско средство</i>
sv	<i>Medicinteknisk produkt</i>
tr	<i>Tıbbi cihaz</i>


	
pt	<i>Contém sangue humano ou derivados de plasma</i>
ro	<i>Conține sânge uman sau derivate din plasmă</i>
ru	<i>Содержит кровь человека или производные плазмы</i>
sk	<i>Obsahuje ľudskú krv alebo deriváty plazmy</i>
sl	<i>Vsebuje derivate človeške krvi ali plazme</i>
sr	<i>Садржи људску крв или деривате плазме</i>
sv	<i>Innehåller humant blod eller plasmaderivat</i>
tr	<i>İnsan kanı veya plazma türevleri içerir</i>


	
en	<b>Contains a medicinal substance</b>
de	<i>Enthält ein Arzneimittel</i>
fr	<i>Contient une substance médicinale</i>
bg	<i>Съдържа лекарствено вещество</i>
cs	<i>Obsahuje léčivou látku</i>
da	<i>Indeholder et lægemiddel</i>
el	<i>Περιέχει φαρμακευτική ουσία</i>
es	<i>Contiene una sustancia medicinal</i>
et	<i>Sisaldab ravainet</i>
fi	<i>Sisältää lääkeainetta</i>
hr	<i>Sadrži ljekovitu tvar</i>
hu	<i>Gyógyszert tartalmaz</i>
it	<i>Contiene una sostanza medicinale</i>
lt	<i>Sudėtyje yra vaistinės medžiagos</i>
lv	<i>Satur zāles</i>

	
en	<b>Contains hazardous substances</b>
de	<i>Enthält Gefahrstoffe</i>
fr	<i>Contient des substances dangereuses</i>
bg	<i>Съдържа опасни вещества</i>
cs	<i>Obsahuje nebezpečné látky</i>
da	<i>Indeholder farlige stoffer</i>
el	<i>Περιέχει επικίνδυνη ουσία</i>
es	<i>Contiene sustancias peligrosas</i>
et	<i>Sisaldab ohtlikku ainet</i>
fi	<i>Sisältää vaarallisia aineita</i>
hr	<i>Sadrži opasne tvari</i>
hu	<i>Veszélyes anyagot tartalmaz</i>
it	<i>Contiene sostanze pericolose</i>
lt	<i>Sudėtyje yra pavojingų medžiagų</i>
lv	<i>Satur bīstamu vielu</i>

	
nl	<i>Bevat een geneesmiddel</i>
no	<i>Inneholder et medisinsk stoff</i>
pl	<i>Zawiera substancję leczniczą</i>
pt	<i>Contém uma substância medicinal</i>
ro	<i>Conține o substanță medicamentoasă</i>
ru	<i>Содержит лекарственное вещество</i>
sk	<i>Obsahuje liečivú látku</i>
sl	<i>Vsebuje zdravilno učinkovino</i>
sr	<i>Садржи лековиту супстанцу</i>
sv	<i>Innehåller ett läkemedel</i>
tr	<i>Tıbbi bir madde içerir</i>


	
nl	<i>Bevat gevaarlijke stoffen</i>
no	<i>Inneholder farlige stoffer</i>
pl	<i>Zawiera niebezpieczne substancje</i>
pt	<i>Contém substâncias perigosas</i>
ro	<i>Conține substanțe periculoase</i>
ru	<i>Содержит опасные вещества</i>
sk	<i>Obsahuje nebezpečné látky</i>
sl	<i>Vsebuje nevarno snov</i>
sr	<i>Садржи опасне супстанце</i>
sv	<i>Innehåller farliga ämnen</i>
tr	<i>Tehlikeli madde içerir</i>

	
en	<b>Contains biological material of human origin</b>
de	<i>Enthält biologisches Material menschlichen Ursprungs</i>
fr	<i>Contient une substance biologique d'origine humaine</i>
bg	<i>Съдържа биологичен материал от човешки произход</i>
cs	<i>Obsahuje biologický materiál lidského původu</i>
da	<i>Indeholder biologisk materiale af human oprindelse</i>
el	<i>Περιέχει βιολογικό υλικό ανθρώπινης προέλευσης</i>
es	<i>Contiene material biológico de origen humano</i>
et	<i>Sisaldab inimäritolu bioloogilist materjali</i>
fi	<i>Sisältää ihmisperäistä biologista materiaalia</i>

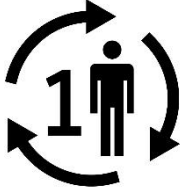
	
en	<b>Contains biological material of animal origin</b>
de	<i>Enthält biologisches Material tierischen Ursprungs</i>
fr	<i>Contient une substance biologique d'origine animale</i>
bg	<i>Съдържа биологичен материал от животински произход</i>
cs	<i>Obsahuje biologický materiál zvířecího původu</i>
da	<i>Indeholder biologisk materiale af animalsk oprindelse</i>
el	<i>Περιέχει βιολογικό υλικό ζωικής προέλευσης</i>
es	<i>Contiene material biológico de origen animal</i>
et	<i>Sisaldab loomset päritolu bioloogilist materjali</i>
fi	<i>Sisältää eläinperäistä biologista materiaalia</i>



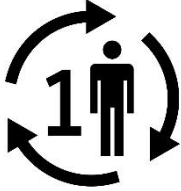
	
hr	<i>Sadrži biološki materijal ljudskog podrijetla</i>
hu	<i>Emberi eredetű biológiai anyagot tartalmaz</i>
it	<i>Contiene materiale biologico di origine umana</i>
lt	<i>Sudėtyje yra žmogaus kilmės biologinės medžiagos</i>
lv	<i>Satur cilvēka izcelsmes bioloģisko materiālu</i>
nl	<i>Bevat biologisch materiaal van menselijke oorsprong</i>
no	<i>Inneholder biologisk materiale av human opprinnelse</i>
pl	<i>Zawiera materiał biologiczny pochodzenia ludzkiego</i>
pt	<i>Contém material biológico de origem humana</i>
ro	<i>Conține material biologic de origine umană</i>
ru	<i>Содержит биологический материал человеческого происхождения</i>
sk	<i>Obsahuje biologický materiál ľudského pôvodu</i>
sl	<i>Vsebuje biološki material človeškega izvora</i>
sr	<i>Садржи биолошки материјал људског порекла</i>
sv	<i>Innehåller biologiskt material av mänskligt ursprung</i>
tr	<i>İnsan kökenli biyolojik materyal içerir</i>

	
hr	<i>Sadrži biološki materijal životinjskog podrijetla</i>
hu	<i>Állati eredetű biológiai anyagot tartalmaz</i>
it	<i>Contiene materiale biologico di origine animale</i>
lt	<i>Sudėtyje yra gyvūninės kilmės biologinės medžiagos</i>
lv	<i>Satur dzīvnieku izcelsmes bioloģisko materiālu</i>
nl	<i>Bevat biologisch materiaal van dierlijke oorsprong</i>
no	<i>Inneholder biologisk materiale av animalsk opprinnelse</i>
pl	<i>Zawiera materiał biologiczny pochodzenia zwierzęcego</i>
pt	<i>Contém material biológico de origem animal</i>
ro	<i>Conține material biologic de origine animală</i>
ru	<i>Содержит биологический материал животного происхождения</i>
sk	<i>Obsahuje biologický materiál živočíšneho pôvodu</i>
sl	<i>Vsebuje biološki material živalskega izvora</i>
sr	<i>Садржи биолошки материјал животињског порекла</i>
sv	<i>Innehåller biologiskt material av animaliskt ursprung</i>
tr	<i>Hayvan kökenli biyolojik materyal içerir</i>

<div style="border: 2px solid black; padding: 5px; display: inline-block;"> <b>STERILE   VH2O2</b> </div>	
en	<b>Sterilized using vaporized hydrogen peroxide</b>
de	<i>Sterilisiert mit verdampftem Wasserstoffperoxid</i>
fr	<i>Stérilisé par peroxyde d'hydrogène vaporisé</i>
bg	<i>Стерилизирано с изпарен водороден пероксид</i>
cs	<i>Sterilizováno za použití odpařeného peroxidu vodíku</i>
da	<i>Steriliseret med vaporiseret hydrogenperoxid</i>
el	<i>Αποστειρωμένο με τη χρήση εξατμισμένου υπεροξειδίου του υδρογόνου</i>
es	<i>Esterilizado utilizando peróxido de hidrógeno vaporizado</i>
et	<i>Steriliseeritud aurutatud vesinikperoksiidiga</i>
fi	<i>Steriloitu vetyperoksidihöyryllä</i>
hr	<i>Sterilizirano vaporiziranim vodikovim peroksidom</i>
hu	<i>Gőzfázisú hidrogén-peroxiddal sterilizálva</i>
it	<i>Sterilizzato utilizzando perossido di idrogeno vaporizzato</i>
lt	<i>Sterilizuotas naudojant garintąjį vandenilio peroksidą</i>
lv	<i>Sterilizēts, izmantojot iztvaicētu ūdeņraža peroksīdu</i>
nl	<i>Gesteriliseerd met verdampt waterstofperoxide</i>
no	<i>Sterilisert ved bruk av fordampet hydrogenperoksid</i>
pl	<i>Steryliżowane za pomocą odparowanego nadtlenku wodoru</i>
pt	<i>Esterilizado por peróxido de hidrogénio vaporizado</i>
ro	<i>Sterilizat cu vapori de peroxid de hidrogen</i>

	
en	<b>Single Patient - multiple use</b>
de	<i>Einzelner Patient – mehrfach anwendbar</i>
fr	<i>Un seul patient – à usage multiple</i>
bg	<i>Един пациент – многократна употреба</i>
cs	<i>Jeden pacient – vícenásobné použití</i>
da	<i>Enkelt patient – flergangsbrug</i>
el	<i>Πολλαπλή χρήση – σε έναν μόνο ασθενή</i>
es	<i>Un solo paciente – uso múltiple</i>
et	<i>Ühel patsiendil korduvalt kasutatav</i>
fi	<i>Potilaskohtainen – voidaan käyttää useita kertoja</i>
hr	<i>Jedan pacijent – višestruka uporaba</i>
hu	<i>Egyetlen beteg esetében többször újrahasználató</i>
it	<i>Singolo paziente – uso multiplo</i>
lt	<i>Vienas pacientas – daugkartinis naudojimas</i>
lv	<i>Viens pacients – vairākkārtēja lietošana</i>
nl	<i>Eén patiënt – meervoudig gebruik</i>
no	<i>Kun til bruk på én pasient – flergangsbruk</i>
pl	<i>Wielokrotne użycie u jednego pacjenta”</i>
pt	<i>Paciente único – várias utilizações</i>
ro	<i>Un singur pacient – utilizare multiplă</i>

<b>STERILE   VH202</b>	
ru	<i>Стерилизовано с использованием испаренной перекиси водорода</i>
sk	<i>Sterilizované použitím odpareného peroxidu vodíka</i>
sl	<i>Steriliziramo z uparjenim vodikovim peroksidom</i>
sr	<i>Стерилизовано коришћењем испареног водоник пероксида</i>
sv	<i>Steriliserad med förångad väteperoxid</i>
tr	<i>Buharlaştırılmış hidrojen peroksit kullanılarak sterilize edildi</i>

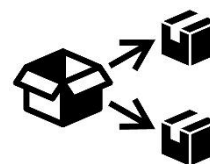
	
ru	<i>Многократное использование для одного пациента</i>
sk	<i>Jeden pacient – viacnásobné použitie</i>
sl	<i>En bolnik – večkratna uporaba</i>
sr	<i>Један пацијент – вишеструка употреба</i>
sv	<i>En patient – flera användningar</i>
tr	<i>Tek hasta – çoklu kullanım</i>

	
en	<b>Translation</b>
de	<i>Übersetzung</i>
fr	<i>Traduction</i>
bg	<i>Превод</i>
cs	<i>Překlad</i>
da	<i>Oversættelse</i>
el	<i>Μετάφραση</i>
es	<i>Traducción</i>
et	<i>Tõlge</i>
fi	<i>Käännös</i>
hr	<i>Prijevod</i>
hu	<i>Fordítás</i>
it	<i>Traduzione</i>
lt	<i>Vertimas</i>
lv	<i>Tulkošana</i>
nl	<i>Vertaling</i>
no	<i>Oversettelse</i>
pl	<i>Tłumaczenie</i>

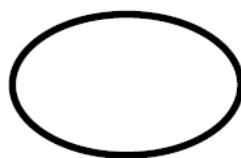
	
en	<b>Repackaging</b>
de	<i>Umpacken</i>
fr	<i>Reconditionnement</i>
bg	<i>Преупаковане</i>
cs	<i>Přebalení</i>
da	<i>Ompakning</i>
el	<i>Επανασυσκευασία</i>
es	<i>Reembalado</i>
et	<i>Ümberpakendamine</i>
fi	<i>Uudelleenpakkaus</i>
hr	<i>Promjena pakiranja</i>
hu	<i>Újracsomagolás</i>
it	<i>Riconfezionamento</i>
lt	<i>Perpakavimas</i>
lv	<i>Pārpackošana</i>
nl	<i>Herverpakking</i>
no	<i>Ompakking</i>
pl	<i>Przepakowanie</i>



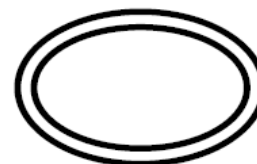
pt	<i>Tradução</i>
ro	<i>Traducere</i>
ru	<i>Перевод</i>
sk	<i>Preklad</i>
sl	<i>Prevod</i>
sr	<i>Превод</i>
sv	<i>Översättning</i>
tr	<i>Tercüme</i>



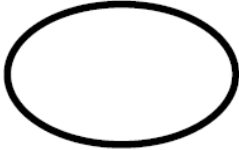
pt	<i>Reembalagem</i>
ro	<i>Reambalare</i>
ru	<i>Смена упаковки</i>
sk	<i>Prebaľovanie</i>
sl	<i>Prepakiranje</i>
sr	<i>Поновно паковање</i>
sv	<i>Ompaketering</i>
tr	<i>Yeniden ambalajlama</i>

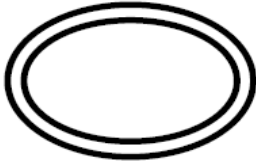



en	<b>Single sterile barrier system</b>
de	<i>Einfaches Sterilbarrieresystem</i>
fr	<i>Système de barrière stérile simple</i>
bg	<i>Единична стерилна бариерна система</i>
cs	<i>Jednoduchý systém sterilní bariéry</i>
da	<i>System med enkelt steril barriere</i>
el	<i>Σύστημα μονού στείρου φραγμού</i>
es	<i>Sistema de barrera estéril única</i>
et	<i>Ühekordne steriilne kaitsemeetod</i>
fi	<i>Yksinkertainen steriili estejärjestelmä</i>
hr	<i>Sustav jednostruke sterilne barijere</i>
hu	<i>Egyszeres steril határolórendszer</i>
it	<i>Sistema di barriera sterile singola</i>
lt	<i>Vieno sterilaus barjero sistema</i>
lv	<i>Sistēma ar vienu sterilo barjeru</i>
nl	<i>Toepassing van een enkelvoudige steriele barrière</i>
no	<i>Enkelt sterilt barrieresystem</i>

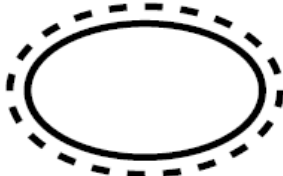



en	<b>Double sterile barrier system</b>
de	<i>Doppeltes Sterilbarrieresystem</i>
fr	<i>Système de barrière stérile double</i>
bg	<i>Двойна стерилна бариерна система</i>
cs	<i>Dvojitý systém sterilní bariéry</i>
da	<i>System med dobbelt steril barriere</i>
el	<i>Σύστημα διπλού στείρου φραγμού</i>
es	<i>Sistema de barrera estéril doble</i>
et	<i>Kahekordne steriilne kaitsemeetod</i>
fi	<i>Kaksinkertainen steriili estejärjestelmä</i>
hr	<i>Sustav dvostruke sterilne barijere</i>
hu	<i>Dupla steril határolórendszer</i>
it	<i>Sistema di barriera sterile doppia</i>
lt	<i>Dvigubo sterilaus barjero sistema</i>
lv	<i>Sistēma ar dubultu sterilo barjeru</i>
nl	<i>Toepassing van een dubbele steriele barrière</i>
no	<i>Dobbelt sterilt barrieresystem</i>


	
pl	<i>System pojedynczej bariery sterylnej</i>
pt	<i>Sistema de barreira única estéril</i>
ro	<i>Sistem cu barieră sterilă unică</i>
ru	<i>Оди́нарная стерильная барьерная система</i>
sk	<i>Systém s jednou sterilnou bariérou</i>
sl	<i>Sistem enojne sterilne pregrade</i>
sr	<i>Систем са једном стерилном баријером</i>
sv	<i>System med enkel sterilbarriär</i>
tr	<i>Tekli steril bariyer sistemi</i>

	
pl	<i>System podwójnej bariery sterylnej</i>
pt	<i>Sistema de barreira dupla estéril</i>
ro	<i>Sistem cu barieră sterilă dublă</i>
ru	<i>Двойная стерильная барьерная система</i>
sk	<i>Systém s dvojitou sterilnou bariérou</i>
sl	<i>Sistem dvojne sterilne pregrade</i>
sr	<i>Систем двоструке стерилне баријере</i>
sv	<i>System med dubbel sterilbarriär</i>
tr	<i>Çift steril bariyer sistemi</i>

	
en	<b>Single sterile barrier system with protective packaging inside</b>
de	<i>Einfaches Sterilbarrieresystem mit Schutzverpackung innen</i>
fr	<i>Système de barrière stérile simple avec emballage de protection interne</i>
bg	<i>Единична стерилна бариерна система с вътрешна защитна опаковка</i>
cs	<i>Jednoduchý systém sterilní bariéry s ochranným balením uvnitř</i>
da	<i>System med enkelt steril barriere med indvendig beskyttelsesemballage</i>

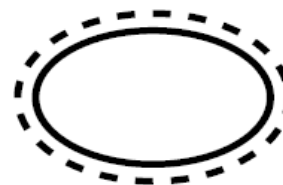
	
en	<b>Single sterile barrier system with protective packaging outside</b>
de	<i>Einfaches Sterilbarrieresystem mit Schutzverpackung außen</i>
fr	<i>Système de barrière stérile simple avec emballage de protection externe</i>
bg	<i>Единична стерилна бариерна система с външна защитна опаковка</i>
cs	<i>Jednoduchý systém sterilní bariéry s ochranným balením vně</i>
da	<i>System med enkelt steril barriere med udvendig beskyttelsesemballage</i>

	
el	<i>Σύστημα μονού στείρου φραγμού με προστατευτική εσωτερική συσκευασία</i>
es	<i>Sistema de barrera estéril única con embalaje protector interior</i>
et	<i>Ühekordne steriilne kaitsemeetod seesmise kaitsepakendiga</i>
fi	<i>Yksinkertainen steriili estejärjestelmä ja sisäpuolinen suojarahkaus</i>
hr	<i>Sustav jednostruke sterilne barijere sa zaštitnim pakiranjem iznutra</i>
hu	<i>Egyszeres steril határolórendszer belső védőcsomagolással</i>
it	<i>Sistema di barriera sterile singola con confezione protettiva interna</i>
lt	<i>Vieno sterilaus barjero sistema su vidine apsaugine pakuote</i>
lv	<i>Sistēma ar vienu sterilo barjeru un aizsargiepakojumu iekšpusē</i>
nl	<i>Toepassing van een enkelvoudige steriele barrière rondom een beschermende verpakking</i>
no	<i>Enkelt sterilt barrieresystem med beskyttende emballasje inni</i>
pl	<i>System pojedynczej bariery sterylnej z wewnętrznym opakowaniem ochronnym</i>
pt	<i>Sistema de barreira única estéril com embalagem de proteção interna</i>
ro	<i>Sistem cu barieră sterilă unică cu ambalaj de protecție interior</i>
ru	<i>Одинарная стерильная барьерная система с защитной упаковкой внутри</i>
sk	<i>Systém s jednou sterilnou bariérou s ochranným obalom vnútri</i>

	
el	<i>Σύστημα μονού στείρου φραγμού με προστατευτική εξωτερική συσκευασία</i>
es	<i>Sistema de barrera estéril única con embalaje protector exterior</i>
et	<i>Ühekordne steriilne kaitsemeetod välise kaitsepakendiga</i>
fi	<i>Yksinkertainen steriili estejärjestelmä ja ulkopuolinen suojarahkaus</i>
hr	<i>Sustav jednostruke sterilne barijere sa zaštitnim pakiranjem izvana</i>
hu	<i>Egyszeres steril határolórendszer külső védőcsomagolással</i>
it	<i>Sistema di barriera sterile singola con confezione protettiva esterna</i>
lt	<i>Vieno sterilaus barjero sistema su išorine apsaugine pakuote</i>
lv	<i>Sistēma ar vienu sterilo barjeru un aizsargiepakojumu ārpusē</i>
nl	<i>Toepassing van een enkelvoudige steriele barrière binnen een beschermende verpakking</i>
no	<i>Enkelt sterilt barrieresystem med beskyttende emballasje utenpå</i>
pl	<i>System pojedynczej bariery sterylnej z zewnętrznym opakowaniem ochronnym</i>
pt	<i>Sistema de barreira única estéril com embalagem de proteção externa</i>
ro	<i>Sistem cu barieră sterilă unică cu ambalaj de protecție exterior</i>
ru	<i>Одинарная стерильная барьерная система с защитной упаковкой снаружи</i>
sk	<i>Systém s jednou sterilnou bariérou s ochranným obalom vonku</i>



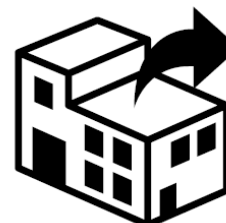
sl	<i>Sistem enojne sterilne pregrade z notranjo zaščitno ovojnino</i>
sr	<i>Систем са једном стерилном баријером и унутрашњом заштитном амбалажом</i>
sv	<i>System med enkel sterilbarriär och skyddsförpackning inuti</i>
tr	<i>İçerisinde koruyucu ambalaj bulunan tekli steril bariyer sistemi</i>



sl	<i>Sistem enojne sterilne pregrade z zunanjo zaščitno ovojnino</i>
sr	<i>Систем са једном стерилном баријером и спољашњом заштитном амбалажом</i>
sv	<i>System med enkel sterilbarriär och skyddsförpackning utanpå</i>
tr	<i>Dişında koruyucu ambalaj bulunan tekli steril bariyer sistemi</i>



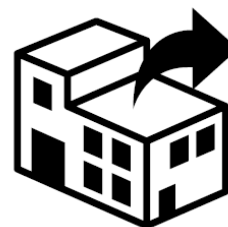
en	<b>Importer</b>
de	<i>Importeur</i>
fr	<i>Importateur</i>
bg	<i>Вносител</i>
cs	<i>Dovozce</i>
da	<i>Importør</i>
el	<i>Εισαγωγέας</i>
es	<i>Importador</i>
et	<i>Importija</i>
fi	<i>Maahantuoja</i>
hr	<i>Uvoznik</i>
hu	<i>Importőr</i>
it	<i>Importatore</i>
lt	<i>Importuotojas</i>
lv	<i>Importētājs</i>
nl	<i>Importeur</i>



en	<b>Distributor</b>
de	<i>Vertreiber</i>
fr	<i>Distributeur</i>
bg	<i>Дистрибутор</i>
cs	<i>Distributor</i>
da	<i>Distributør</i>
el	<i>Διανομέας</i>
es	<i>Distribuidor</i>
et	<i>Edasimüüja</i>
fi	<i>Jälleenmyyjä</i>
hr	<i>Distributer</i>
hu	<i>Forgalmazó</i>
it	<i>Distributore</i>
lt	<i>Platintojas</i>
lv	<i>Izplatītājs</i>
nl	<i>Distributeur</i>



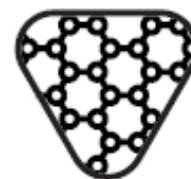
no	<i>Importør</i>
pl	<i>Importer</i>
pt	<i>Importador</i>
ro	<i>Importator</i>
ru	<i>Импортер</i>
sk	<i>Dovozca</i>
sl	<i>Uvoznik</i>
sr	<i>Увозник</i>
sv	<i>Importör</i>
tr	<i>İthalatçı</i>



no	<i>Distributør</i>
pl	<i>Dystrybutor</i>
pt	<i>Distribuidor</i>
ro	<i>Distribuitor</i>
ru	<i>Дистрибьютор</i>
sk	<i>Distribútor</i>
sl	<i>Distributer</i>
sr	<i>Дистрибутер</i>
sv	<i>Distributör</i>
tr	<i>Distribütör</i>





en	<b>Unique Device Identification</b>
de	<i>Eindeutige Gerätekennung</i>
fr	<i>Identifiant de dispositif unique</i>
bg	<i>Уникален идентификатор на изделието</i>
cs	<i>Jedinečný identifikátor prostředku</i>
da	<i>Unik enhedsidentifikator</i>
el	<i>Μοναδικός αναγνωριστικός κωδικός προϊόντος</i>
es	<i>Identificación única de producto</i>
et	<i>Kordumatu identifitseerimistunnus</i>
fi	<i>Yksilöllinen laitetunniste</i>
hr	<i>Jedinstvena identifikacijska oznaka proizvoda</i>
hu	<i>Egyedi eszközazonosító</i>



en	<b>Contains nano materials</b>
de	<i>Enthält Nanomaterialien</i>
fr	<i>Contient des nanomatériaux</i>
bg	<i>Съдържа наноматериали</i>
cs	<i>Obsahuje nanomateriály</i>
da	<i>Indeholder nano-materialer</i>
el	<i>Περιέχει νανοϋλικά</i>
es	<i>Contiene nanomateriales</i>
et	<i>Sisaldab nanomaterjale</i>
fi	<i>Sisaldab nanomaterjale Sisältää nano-materiaaleja</i>
hr	<i>Sadrži nanomaterijale</i>
hu	<i>Nanoanyagokat tartalmaz</i>



	
it	<i>Identificatore univoco del dispositivo</i>
lt	<i>Unikalus prietaiso identifikatorius</i>
lv	<i>Unikāls ierīces identifikators</i>
nl	<i>Unieke identificatiecode van het hulpmiddel</i>
no	<i>Unik enhetsidentifikator</i>
pl	<i>Niepowtarzalny identyfikator urządzenia</i>
pt	<i>Identificador de dispositivo único</i>
ro	<i>Identificator unic al dispozitivului</i>
ru	<i>Уникальный идентификатор устройства</i>
sk	<i>Unikátny identifikátor pomôcky</i>
sl	<i>Edinstveni identifikator pripomočka</i>
sr	<i>Јединствени идентификатор средства</i>
sv	<i>Unik enhetsidentifierare</i>
tr	<i>Benzersiz Cihaz Tanımlayıcısı</i>

	
it	<i>Contiene nanomateriali</i>
lt	<i>Sudėtyje yra nanomedžiagų</i>
lv	<i>Satur nano materiālus</i>
nl	<i>Bevat nanomaterialen</i>
no	<i>Inneholder nano-materialer</i>
pl	<i>Zawiera materiały nano</i>
pt	<i>Contém nanomateriais</i>
ro	<i>Conține nanomateriale</i>
ru	<i>Содержит наноматериалы</i>
sk	<i>Obsahuje nano materiály</i>
sl	<i>Vsebuje nanomateriale</i>
sr	<i>Садржи нано материјале</i>
sv	<i>Innehåller nanomaterial</i>
tr	<i>Nano malzemeler içerir</i>








Note: The abbreviations used for the languages are the official short names in English for language names as given in the standard 639-1:2002: Codes for the representation of names of languages -- Part 1: Alpha-2 code:

en = English; de = German / Deutsch; fr= French / Français; bg = Bulgarian / български; cs = Czech / Čeština; da = Danish / Dansk; el= Greek / Ελληνικά; es = Spanish / Español; et = Estonian / Eesti; fi = Finnish / Suomi; hr = Croatian / Hrvatski; hu = Hungarian / Magyar; it= Italian / Italiano; lt = Lithuanian / Lietuvių kalba; lv = Latvian / Latviešu valoda; nl = Dutch / Nederlands; no = Norwegian / Norsk; pl = Polish / Polski; pt= Portuguese / Português; ro = Romanian / Româna; ru = Russian / Русский; sk = Slovak / Slovenčina; sl = Slovenian / Slovenski; sr = Serbian / Srpski; sv = Swedish / Svenska; tr = Turkish / Türkçe.

## Annex II

### Recommended symbols for use with the patient implant card

- As an alternative to text
- Based on requirements of **MDR Art.18** MTE recommends the following symbols
- The symbols below can either be found on the [ISO Online Browsing Platform](https://www.iso.org/obp) (<https://www.iso.org/obp>) or in ISO 15223-1:2021. If a symbol is registered in ISO 7000 its numerical reference is included next to the symbol title. Otherwise, symbols not registered in ISO 7000 are found only within ISO 15223-1:2021

<p><b>Patient identification</b> (5664)</p>	
<p><b>Medical device</b></p> <ul style="list-style-type: none"> <li>- included in ISO 15223-1:2021, not in ISO 7000</li> <li>- MDR 2017/745 – Art. 18 - §1d (linked with Annex I §23.2q)</li> <li>- The MDCG guidance on implant cards (<a href="#">MDCG 2019-8 v2</a>) uses this symbol to indicate 'device name'</li> </ul>	
<p><b>Health care centre or doctor</b> (PI PF 044)</p>	
<p><b>Date</b> (5662)</p> <ul style="list-style-type: none"> <li>- to indicate the date of implantation</li> </ul>	
<p><b>Patient information website</b> (3705)</p>	
<p><b>Manufacturer</b> (3082)</p>	
<p><b>Batch code</b> (2492) <u>or</u> <b>Serial number</b> (2498)</p>	

**Unique Device Identifier**

- included in ISO 15223-1:2021, not in ISO 7000





## Annex III (for reference only)

### Summary of changes to symbols between May 2019 & December 2019



**Contains human blood or plasma derivatives**

- technical adjustment of the graphic

<p>May 2019</p> 	<p>November 2019</p> 
---------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------



**Contains a medicinal substance**

- technical adjustment of the graphic

<p>May 2019</p> 	<p>November 2019</p> 
----------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------



**Contains hazardous substances**

- the original exclamation mark was replaced with an ISO aligned exclamation mark.

<p>May 2019</p> 	<p>November 2019</p> 
-----------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------



**Single Patient - multiple use**

- technical adjustment of the graphic

<p>May 2019</p> 	<p>November 2019</p> 
-----------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------

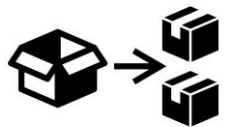
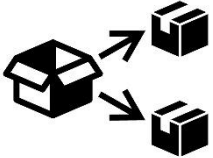
**Translation**

- The original arrow was replaced with an ISO aligned arrow

<p>May 2019</p> 	<p>November 2019</p> 
---------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------

**Repackaging**

- One arrow was replaced by two arrows to reinforce the meaning

<p>May 2019</p> 	<p>November 2019</p> 
---------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------

## References\*:

- MD Regulation 2017/745/EU

\*For EU legislation please see latest consolidated version. For MedTech Europe documents, in case any links are broken, please consult the latest version under the [Regulatory E-Library](#) (for members only).

- ISO 15223-1 (2021) *2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements.*

## About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit [www.medtecheurope.org](http://www.medtecheurope.org).

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