Use of Symbols to Indicate Compliance with the MDR

December 2019

Version 2.0 (replaces original version of May 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. To comply with this requirement within the short term and in a harmonised manner, before the international standard is available, MedTech Europe publishes the present guidance on symbols for the following information:

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

Additionally, in Annex 2 of the present guidance MedTech Europe recommends ***symbols to be used with patient implant card.***

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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.

MedTech Europe went through a vigorous process of discussion, design and user validation according to international standards to deliver the symbols present in this guidance. The symbols are scalable and recognizable at even 5 mm height. 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.

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:

1. **Medical device**
   MDR, Annex 1, 23.2, q.
2. **Contains human blood or plasma derivatives**
   MDR, Annex 1, 23.2, e.
3. **Contains a medicinal substance**
   MDR, Annex 1, 23.2, e
4. **Contains hazardous substances**
   MDR Annex 1, 23.2.(f)
   ISO CD 15223-1, 5.4.10, description : ''Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.''
   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**
   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**
   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 & 9. Repackaging**

   - 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.'*
   - This is a requirement referring to economic operators **other than the legal manufacturer**
   - The symbol is for use of those entities to comply with the MDR

At the same time, Medtech Europe recommends the use of the present symbol for the 'Single patient - multiple use' meaning. This symbol has been equally validated according to international standards with healthcare professionals and patients. Its use is supported by references in the ISO and IMDRF documents.

10. **Single Patient – Multiple use**

    - IMDRF draft on ''*Principles of Labelling for Medical Devices and IVD Medical Devices''*, *GRRP WG (PD1)/N52: July 2018), Art. 5.2.17*: ''If the medical device or IVD medical device is intended by the manufacturer for single-use only, reuse on a single patient, and/or reuse on more than one patient, the label should indicate this.''
    - ISO/DIS 20417 2019 Section 3.26: definition of *single patient reuse* (alignment requested with wording of 15223-1; 'Single patient - multiple use')

Harmonization- validation

MedTech Europe has performed a validation of the following symbols and their meanings, 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*) and has presented the results to the ISO TC 210 WG 3. The validation was run in 5 languages in multiple geographies and included patients and healthcare providers.

Based on the validation results and the ISO TC 210 WG 3 feedback, we present the symbols in Annex I of this document with descriptions in all 24 EU official languages:

- Medical device
- Contains hazardous substances
- Contains biological material of human origin
- Contains biological material of animal origin

- Single Patient - multiple use
- Translation
- Repackaging

One of MTE's members performed validation of symbols in line with the above-mentioned ISO 15223-2 process for the following meanings:

- Contains human blood or plasma derivatives
- Contains a medicinal substance
- Sterilized using vaporized hydrogen peroxide

These are equally being endorsed by the present industry guidance and recommended for use, since they have also been submitted to the ISO TC 210 WG 3.

Given the extent and length of complying with ISO process, the inclusion of these symbols would not be timely for the compliance with MDR on 26 May 2020. This guidance can be used from now on to ensure a harmonized approach until the updated version of the ISO 15223-1 (*Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements)* is released.

New! Current state of play (December 2019)

All the symbols included in this guidance are firmly included in the 15223-1 revision process and are foreseen for publication in this standard. The following symbols, some with minor updates, which can be consulted in Annex III, were also approved by the ISO Technical Committee (TC) 145 and included in ISO 7000 database. Hence, they are already available on the ISO Online Browsing Platform (OBP): https://www.iso.org/obp/ui/#home

Contains human blood or plasma derivatives
Contains a medicinal substance
Contains hazardous substances
Contains biological material of human origin
Contains biological material of animal origin
Translation
Repackaging
Single Patient Multiple use

Please note that the symbols for *''Medical device''*, *''Sterilized using vaporized hydrogen peroxide''* and *''Unique Device Identification''* were not approved by the TC 145 for inclusion in the ISO 7000 database and will therefore not be available on the OBP. They are still part of the ISO 15223-1 revision and foreseen to be published in this standard.

A note on the use of symbols

These symbols can be used internationally. ***They must be described in the Instructions for Use in line with the MDR 23.1. h) until they are published in a harmonised 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 asks you to keep always the same order** as shown on the attached listing. Using always 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 the attached template** (to avoid any confusion amongst users).

Annex I
Symbol designs, titles and translations

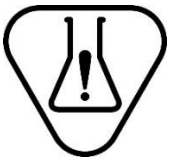
en	**Medical Device**
de	*Medizinprodukt*
fr	*Dispositif médical*
bg	*Медицинско изделие*
cs	*Zdravotnický prostředek*
da	*Medicinsk udstyr*
el	*Ιατροτεχνολογικό προϊόν*
es	*Producto sanitario*
et	*Meditsiiniseade*
fi	*Lääkinnällinen laite*
hr	*Medicinski proizvod*
hu	*Orvostechnikai eszköz*
it	*Dispositivo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

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

ro	*Dispozitiv medical*
ru	*Медицинское изделие*
sk	*Zdravotnícka pomôcka*
sl	*Medicinski pripomoček*
sr	*Медицинско средство*
sv	*Medicinteknisk produkt*
tr	*Tıbbi cihaz*

ro	*Conține sânge uman sau derivate din plasmă*
ru	*Содержит кровь человека или производные плазмы*
sk	*Obsahuje ľudskú krv alebo deriváty plazmy*
sl	*Vsebuje derivate človeške krvi ali plazme*
sr	*Садржи људску крв или деривате плазме*
sv	*Innehåller humant blod eller plasmaderivat*
tr	*İnsan kanı veya plazma türevleri içerir*

en	**Contains a medicinal substance**
de	*Enthält ein Arzneimittel*
fr	*Contient une substance médicinale*
bg	*Съдържа лекарствено вещество*
cs	*Obsahuje léčivou látku*
da	*Indeholder et lægemiddel*
el	*Περιέχει φαρμακευτική ουσία*
es	*Contiene una sustancia medicinal*
et	*Sisaldab raviainet*
fi	*Sisältää lääkeainetta*
hr	*Sadrži ljekovitu tvar*
hu	*Gyógyszert tartalmaz*
it	*Contiene una sostanza medicinale*
lt	*Sudėtyje yra vaistinės medžiagos*
lv	*Satur zāles*
nl	*Bevat een geneesmiddel*
no	*Inneholder et medisinsk stoff*
pl	*Zawiera substancję leczniczą*
pt	*Contém uma substância medicinal*
ro	*Conține o substanță medicamentoasă*
ru	*Содержит лекарственное вещество*



en	**Contains hazardous substances**
de	*Enthält Gefahrstoffe*
fr	*Contient des substances dangereuses*
bg	*Съдържа опасни вещества*
cs	*Obsahuje nebezpečné látky*
da	*Indeholder farlige stoffer*
el	*Περιέχει επικίνδυνη ουσία*
es	*Contiene sustancias peligrosas*
et	*Sisaldab ohtlikku ainet*
fi	*Sisältää vaarallisia aineita*
hr	*Sadrži opasne tvari*
hu	*Veszélyes anyagot tartalmaz*
it	*Contiene sostanze pericolose*
lt	*Sudėtyje yra pavojingų medžiagų*
lv	*Satur bīstamu vielu*
nl	*Bevat gevaarlijke stoffen*
no	*Inneholder farlige stoffer*
pl	*Zawiera niebezpieczne substancje*
pt	*Contém substâncias perigosas*
ro	*Conține substanțe periculoase*
ru	*Содержит опасные вещества*

sk	*Obsahuje liečivú látku*
sl	*Vsebuje zdravilno učinkovino*
sr	*Садржи лековиту супстанцу*
sv	*Innehåller ett läkemedel*
tr	*Tıbbi bir madde içerir*

sk	*Obsahuje nebezpečné látky*
sl	*Vsebuje nevarno snov*
sr	*Садржи опасне супстанце*
sv	*Innehåller farliga ämnen*
tr	*Tehlikeli madde içerir*

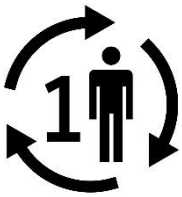
en	**Contains biological material of human origin**
de	*Enthält biologisches Material menschlichen Ursprungs*
fr	*Contient une substance biologique d'origine humaine*
bg	*Съдържа биологичен материал от човешки произход*
cs	*Obsahuje biologický materiál lidského původu*
da	*Indeholder biologisk materiale af human oprindelse*
el	*Περιέχει βιολογικό υλικό ανθρώπινης προέλευσης*
es	*Contiene material biológico de origen humano*
et	*Sisaldab inimpäritolu bioloogilist materjali*
fi	*Sisältää ihmisperäistä biologista materiaalia*
hr	*Sadrži biološki materijal ljudskog podrijetla*
hu	*Emberi eredetű biológiai anyagot tartalmaz*
it	*Contiene materiale biologico di origine umana*
lt	*Sudėtyje yra žmogaus kilmės biologinės medžiagos*
lv	*Satur cilvēka izcelsmes bioloģisko materiālu*
nl	*Bevat biologisch materiaal van menselijke oorsprong*
no	*Inneholder biologisk materiale av human opprinnelse*

en	**Contains biological material of animal origin**
de	*Enthält biologisches Material tierischen Ursprungs*
fr	*Contient une substance biologique d'origine animale*
bg	*Съдържа биологичен материал от животински произход*
cs	*Obsahuje biologický materiál zvířecího původu*
da	*Indeholder biologisk materiale af animalsk oprindelse*
el	*Περιέχει βιολογικό υλικό ζωικής προέλευσης*
es	*Contiene material biológico de origen animal*
et	*Sisaldab loomset päritolu bioloogilist materjali*
fi	*Sisältää eläinperäistä biologista materiaalia*
hr	*Sadrži biološki materijal životinjskog podrijetla*
hu	*Állati eredetű biológiai anyagot tartalmaz*
it	*Contiene materiale biologico di origine animale*
lt	*Sudėtyje yra gyvūninės kilmės biologinės medžiagos*
lv	*Satur dzīvnieku izcelsmes bioloģisko materiālu*
nl	*Bevat biologisch materiaal van dierlijke oorsprong*
no	*Inneholder biologisk materiale av animalsk opprinnelse*

pl	*Zawiera materiał biologiczny pochodzenia ludzkiego*
pt	*Contém material biológico de origem humana*
ro	*Conține material biologic de origine umană*
ru	*Содержит биологический материал человеческого происхождения*
sk	*Obsahuje biologický materiál ľudského pôvodu*
sl	*Vsebuje biološki material človeškega izvora*
sr	*Садржи биолошки материјал људског порекла*
sv	*Innehåller biologiskt material av mänskligt ursprung*
tr	*İnsan kökenli biyolojik materyal içerir*

pl	*Zawiera materiał biologiczny pochodzenia zwierzęcego*
pt	*Contém material biológico de origem animal*
ro	*Conține material biologic de origine animală*
ru	*Содержит биологический материал животного происхождения*
sk	*Obsahuje biologický materiál živočíšneho pôvodu*
sl	*Vsebuje biološki material živalskega izvora*
sr	*Садржи биолошки материјал животињског порекла*
sv	*Innehåller biologiskt material av animaliskt ursprung*
tr	*Hayvan kökenli biyolojik materyal içerir*

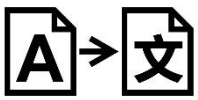
en	**Sterilized using vaporized hydrogen peroxide**
de	*Sterilisiert mit verdampftem Wasserstoffperoxid*
fr	*Stérilisé par peroxyde d'hydrogène vaporisé*
bg	*Стерилизирано с изпарен водороден пероксид*
cs	*Sterilizováno za použití odpařeného peroxidu vodíku*
da	*Steriliseret med vaporiseret hydrogenperoxid*
el	*Αποστειρωμένο με τη χρήση εξατμισμένου υπεροξειδίου του υδρογόνου*
es	*Esterilizado utilizando peróxido de hidrógeno vaporizado*
et	*Steriliseeritud aurutatud vesinikperoksiidiga*



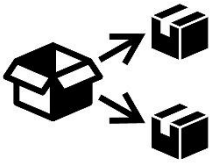
en	**Single Patient - multiple use**
de	*Einzelner Patient – mehrfach anwendbar*
fr	*Un seul patient – à usage multiple*
bg	*Един пациент – многократна употреба*
cs	*Jeden pacient – vícenásobné použití*
da	*Enkelt patient – flergangsbrug*
el	*Πολλαπλή χρήση – σε έναν μόνο ασθενή*
es	*Un solo paciente – uso múltiple*
et	*Ühel patsiendil korduvalt kasutatav*

fi	*Steriloitu vetyperoksidihöyryllä*
hr	*Sterilizirano vaporiziranim vodikovim peroksidom*
hu	*Gőzfázisú hidrogén-peroxiddal sterilizálva*
it	*Sterilizzato utilizzando perossido di idrogeno vaporizzato*
lt	*Sterilizuotas naudojant garintąjį vandenilio peroksidą*
lv	*Sterilizēts, izmantojot iztvaicētu ūdeņraža peroksīdu*
nl	*Gesteriliseerd met verdampt waterstofperoxide*
no	*Sterilisert ved bruk av fordampet hydrogenperoksid*
pl	*Sterylizowane za pomocą odparowanego nadtlenku wodoru*
pt	*Esterilizado por peróxido de hidrogénio vaporizado*
ro	*Sterilizat cu vapori de peroxid de hidrogen*
ru	*Стерилизовано с использованием испаренной перекиси водорода*
sk	*Sterilizované použitím odpareného peroxidu vodíka*
sl	*Steriliziramo z uparjenim vodikovim peroksidom*
sr	*Стерилизовано коришћењем испареног водоник пероксида*
sv	*Steriliserad med förångad väteperoxid*
tr	*Buharlaşmış hidrojen peroksit kullanılarak sterilize edildi*

fi	*Potilaskohtainen – voidaan käyttää useita kertoja*
hr	*Jedan pacijent – višestruka uporaba*
hu	*Egyetlen beteg esetében többször újrahasználható*
it	*Singolo paziente – uso multiplo*
lt	*Vienas pacientas – daugkartinis naudojimas*
lv	*Viens pacients – vairākkārtēja lietošana*
nl	*Eén patiënt – meervoudig gebruik*
no	*Kun til bruk på én pasient – flergangsbruk*
pl	*Wielokrotne użycie u jednego pacjenta”*
pt	*Paciente único – várias utilizações*
ro	*Un singur pacient – utilizare multiplă*
ru	*Многократное использование для одного пациента*
sk	*Jeden pacient – viacnásobné použitie*
sl	*En bolnik – večkratna uporaba*
sr	*Један пацијент – вишеструка употреба*
sv	*En patient – flera användningar*
tr	*Tek hasta – çoklu kullanım*



en	**Translation**
de	*Übersetzung*
fr	*Traduction*



en	**Repackaging**
de	*Umpacken*
fr	*Reconditionnement*

bg	*Превод*
cs	*Překlad*
da	*Oversættelse*
el	*Μετάφραση*
es	*Traducción*
et	*Tõlge*
fi	*Käännös*
hr	*Prijevod*
hu	*Fordítás*
it	*Traduzione*
lt	*Vertimas*
lv	*Tulkošana*
nl	*Vertaling*
no	*Oversettelse*
pl	*Tłumaczenie*
pt	*Tradução*
ro	*Traducere*
ru	*Перевод*
sk	*Preklad*
sl	*Prevod*
sr	*Превод*
sv	*Översättning*
tr	*Tercüme*

bg	*Преопаковане*
cs	*Přebalení*
da	*Ompakning*
el	*Επανασυσκευασία*
es	*Reembalado*
et	*Ümberpakendamine*
fi	*Uudelleenpakkaus*
hr	*Promjena pakiranja*
hu	*Újracsomagolás*
it	*Riconfezionamento*
lt	*Perpakavimas*
lv	*Pārpakošana*
nl	*Herverpakking*
no	*Ompakking*
pl	*Przepakowanie*
pt	*Reembalagem*
ro	*Reambalare*
ru	*Смена упаковки*
sk	*Prebaľovanie*
sl	*Prepakiranje*
sr	*Поновно паковање*
sv	*Ompaketering*
tr	*Yeniden ambalajlama*

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 / Lietuviu 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 numerically referenced symbols are published and available for use via the ISO website: https://www.iso.org/obp/ui/#home
- UDI, MD and Patient information website have been validated by users according to the ISO 15223-2 process.
- All symbols listed here are now with the ISO TC 210 WG 3 for review in the framework of 15223-1 revision.

Person identification (5664)

Medical device
- Currently undergoing ISO process
- MDR 2017/745 – Art. 18 - §1d (linked with Annex I §23.2q)

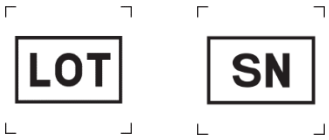
Health care centre or doctor (PI PF 044)

Date (5662)
- to indicate the date of implantation

Patient information website ***New!*** (3705)

Manufacturer (3082)

Batch code (2492) or **Serial number** (2498)



Unique Device Identifier

- currently undergoing ISO process

Annex III
Summary of changes compared to May 2019 version

1) The following paragraph has been added to the guidance:

New! **Current state of play (November 2019)**

2) Changes to the symbols table have been made:

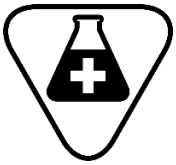
Contains human blood or plasma derivatives

- technical adjustment of the graphic

May 2019	November 2019
	

Contains a medicinal substance

- technical adjustment of the graphic

May 2019	November 2019
	

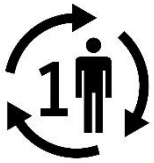
Contains hazardous substances

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

May 2019	November 2019
	

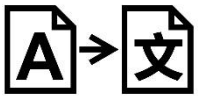
Single Patient - multiple use

- technical adjustment of the graphic

May 2019	November 2019
	

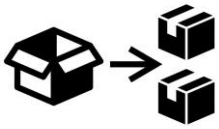
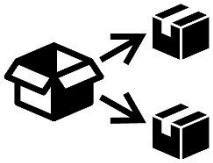
Translation

- The original arrow was replaced with an ISO aligned arrow

May 2019	November 2019
	

Repackaging

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

May 2019	November 2019
	

3) *Annex II 'Patient Information website' symbol has now been updated with the registration number of the ISO online database, since it is now available there.*

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