IVDR – MDR Labelling differences: what symbols apply to IVDs

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The Medical Devices Regulation 2017/745/EU ('MDR') and the In-vitro Devices Regulation 2017/746 (IVDR) both have new requirements for label and packaging of devices. However, these requirements are substantially different from one regulation to another.

The medical devices sector has chosen to address many of the new label requirements by way of symbols that are currently available via the MedTech Europe Industry Guidance and being included in the revision of ISO 15223-1. This paper aims to clarify what symbols developed for the MDR compliance may be potentially used by the IVD sector and which ones are not to be used since the IVDR does not make those kinds of requirements.

1. Sterility symbols

The vast majority of IVDs are not sterilised, hence they will not need symbols indicating sterility. The draft Annex Z for IVDR does refer to the indication of sterile state and the sterilisation method (as these requirements are listed in Annex I IVDR 20.4.1.), where this may apply.

2. Symbols in MedTech Europe Guidance for MDR compliance only

a) the MDR Annex I 23.2.e) outlines specific obligations for manufacturers to indicate on the label the presence of the following:

''a medicinal substance, including a human blood or plasma derivative, or — tissues or cells, or their derivatives, of human origin, or — tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012; ''

The IVDR includes no such requirements.

The MD sector has chosen to address these requirements with dedicated symbols:

	
en	**Contains human blood or plasma derivatives**
	
en	**Contains a medicinal substance**

	
en	**Contains biological material of animal origin**

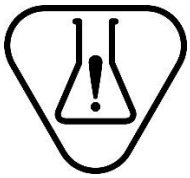
	
en	**Contains biological material of human origin**

Due to the fundamental differences between IVDs and MDs these symbols DO NOT APPLY to IVDs.

If the IVD device contains human material where there is a risk that it could be potentially infectious (IVDR 20.4.1. o)) precautionary statements or the biological risk symbol may need to be used, as applicable. The manufacturer will determine the level of detail of this information in their risk assessment. For more information, you are invited to consult the *MedTech Europe Guidance on Requirements under IVD Regulation 2017/746/EU which drive labelling changes*. *(MedTech Europe members guidance only)*

b) the MDR Annex I 23.2.f) specifies the obligation for manufacturers to indicate on the label the *''presence of: CMR substances and substances with endocrine disrupting properties (in accordance with Section 10.4.5. of MDR).''*

The MD sector addresses this requirement via a symbol:

	
en	**Contains hazardous substances**

Due to the fundamental differences between IVDs and MDs, the IVDR requirements regarding labelling of hazardous substances follow a different path and **do not need the above symbol**. For instance, reagents may contain hazardous substances in order to provoke reactions with the sample but the hazardous substance act on the sample and not on the patient. Similarly, the tendency to encourage substitution of the hazardous substances in MDs present in the MDR does not appear in the IVDR, considering that the IVDs are used only on sample/specimen, not directly on the patient.

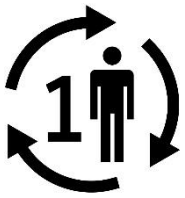
Therefore, for IVDs:

- the label shall include hazard pictograms as per CLP regulation
- the IFU shall contain precautions related to CMR and endocrine disrupting substances according to IVDR Annex I 10.3.

c) **Single Patient Multiple use; ''Indicates a medical device that may be used multiple times (multiple procedures) on a single patient''**.

This is not an MDR explicit requirement but the MD industry found this symbol useful.

This symbol is not applicable to IVDs as <u>they are not used on a patient but on a sample</u>.

	
en	**Single Patient - multiple use**

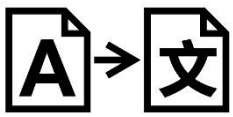
3. New Symbols in ISO 15223-1 DIS that may be used for IVDs

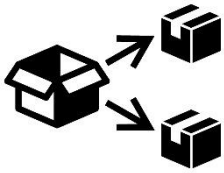
Translation and Repackaging

- IVDR Art. 16.3. 3 requires these activities to be mentioned on the device/ its packaging or accompanying document.
- This requirement refers to economic operators **other than the legal manufacturer,** hence these symbols are to be used only by other economic operators.

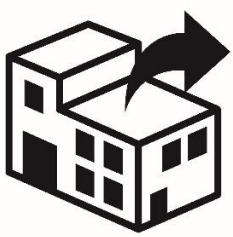
Importer and Distributor symbols

Importer and Distributor symbols have been created to indicate those entities on the device; they can be used in both MD and IVD sectors. Importer and Distributor symbols may be used together with the 'translation' and 'repackaging' symbols.

	
en	**Translation**

	
en	**Repackaging**

	
en	**Importer**

	
en	**Distributor**

References*:

- IVD Regulation 2017/746/EU
- 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).

The *In Vitro* Diagnostic Medical Devices Regulation and the Medical Devices Regulation contain several provisions that are capable of being given more than one interpretation. In the preparation of this Guidance, MedTech Europe has used its best efforts to ensure that the opinions and advice expressed are sound. However, the Association makes no assertion that those opinions and advice are correct and it accepts no legal responsibility for them. Specific legal advice should be sought before acting on any of the topics covered. MedTech Europe reserves the right to change or amend this document at any time without notice in order to keep the information up to date.

Members are reminded that, while competent authorities and notified bodies may be helpful in providing views as to the meaning of the IVD and MD Regulation, it is ultimately for the courts to interpret legislation.

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