MD REGULATORY DIGEST

FOCUS ON

MDR SCOPE & CLASSIFICATION

Here are listed a few points of change related to the scope of devices covered by the Regulation. As a manufacturer and/or a distributor of any of these devices, you will need to pay a special attention to your compliance to the MDR in order to keep them on the European market.

FROM 18 TO 22 CLASSIFICATION RULES

The Regulation goes from 18 medical devices classification rules in the MDD (Medical Device Directive) to 22 rules in the MDR. This means some devices will change class with the new Regulation.

Rule 9 of the MDD on blood bags was integrated to rule 2 of the MDR, and following rules were added:

- Rule 11 on Software,
- Rule 19 on Nanomaterials,
- Rule 20 on Devices intended to administer medicinal products by inhalation,
- Rule 21 on Devices that are composed of substances that are intended to be introduced into the body or applied to the skin,
- Rule 22 on Active therapeutic devices with an integrated or incorporated diagnostic function.

Those devices have specific classification rules and their status were clarified.

If several rules apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.

NON-MEDICAL DEVICES

The Annex XVI lists devices without an intended medical purpose that fall within the scope of the MDR.

Among them, we can cite: contact lenses, breast implants, dermal fillers, equipment for liposuction, lipolysis and lipoplasty, cosmetic laser equipment, transcranial brain stimulation equipment, etc.

All those products also need to meet MDR requirements to stay on the European market.

DEFINITION CHANGES

The definition of a medical device itself was modified and became wider.

Moreover, "surgical intervention" was replaced by "clinical intervention" in the definition of "implantable". This means devices such as IUDs will be considered implantable.

The definition of "custom-made device" was also specified: mass-produced devices shall not be considered to be custom-made devices, even if they need to be adapted to meet specific requirements or if they are produced in accordance with written prescriptions.

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