Special edition part 1

In-Vitro Diagnostic Medical Device Regulation

The new European Regulation No. 2017/ 746 on In-Vitro Diagnostic Medical Devices (IVDR) has now been published and replaces the "IVD Directive" 98/79/EC (IVDD)

Important changes in the regulation of In-Vitro Diagnostic Medical Devices

The new IVD Regulation brings important changes to how IVDs are regulated in the European Community. Several topics which before, have only been addressed in the MEDDEV Guidelines, are now included in the IVDR and are now legally binding. These are, among others, vigilance and post marketing surveillance requirements. Also the necessary content of the technical documentation is now clearly described in the Annex II of the IVDR.

One of the major changes is the introduction of new classification rules which result in a higher classification of some IVDs.

A central European Database as pivotal instrument of registration of devices, safety reports and reporting issues will be established.

Each device will have to be marked with a Unique Device Identifier (UDI).

Transition Periode

The regulation became effective on May 25th 2017 with a transition period of five years. This means that the former In-Vitro Diagnostic Medical Device directive is obsolete from May 26th 2022 and the new IVDR must then be applied.

From November 26th 2022, a registration of all IVDs into EUDAMED is mandatory (if EUDAMED will then have been launched)

Validitiy of Certificates

Probably, the most interesting question for you is the validity of your current or future CE certificates which can be issued according to the old directive 98/79/EC during the transition time:

- CE certificates issued before May 25th 2017 according to the IVDD: remain valid until the given validity date

- CE certificates issued from May 25th 2017 according to the IVDD: remain valid until the end of the period indicated on the certificate, which shall not exceed five years. They shall however become void at the latest on May 25th 2024.

Placing on the market

During the transition period, devices can be placed on the market under the current EU Directives, or the new Regulations (if they fully comply with the new Regulations).

After the end of the transition period the devices certified as explained above can be placed on the market or put into service provided they still comply with the IVDD and there are no significant changes of design and intended use.

However, the requirements of the IVDR relating to post-market surveillance, market surveillance, vigilance, registration of devices must be applied.

Devices that have been CE marked according to the old IVDD, lawfully placed on the market prior to May 26th 2022, and devices placed on the market from May 26th 2022 may continue to be made available on the market or put into service until May 25th 2025.

For more detailed information, please do not hesitate to contact us!

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