Special edition part 1

Medical Device Regulation

The new European Regulation No. 2017/ 745 on Medical Devices (MDR) has now been published and replaces the "Medical Device Directive" 93/42/EEC (MDD)

Important changes in the regulation of Medical Devices

The new Medical Device Regulation brings important changes to how Medical Devices are regulated in the European Community. Several topics which before, have only been addressed in the MEDDEV Guidelines, are now included in the MDR 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 MDR.
One of the major changes is the introduction of new classification rules which may result in a higher classification of some Medical Devices.
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 three years. This means that the former medical device directive is obsolete from May 26th 2020 and the new MDR must then be applied.
From November 26th 2021, a registration of all Medical Devices 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 93/42/EEC during the transition time:

- CE certificates issued before May 25th 2017 according to the MDD: remain valid until the given validity date, except of Annex IV certificates which become void on May 27th 2022 at latest.
- CE certificates issued from May 25th 2017 according to the MDD: 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 27th 2024.

Placing on the market

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 MDD and there are no significant changes of design and intended use.

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

Devices that have been CE marked according to the old MDD, lawfully placed on the market prior to May 26th 2020, and devices placed on the market from May 26th 2020 may continue to be made available on the market or put into service until May 27th 2025.

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

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