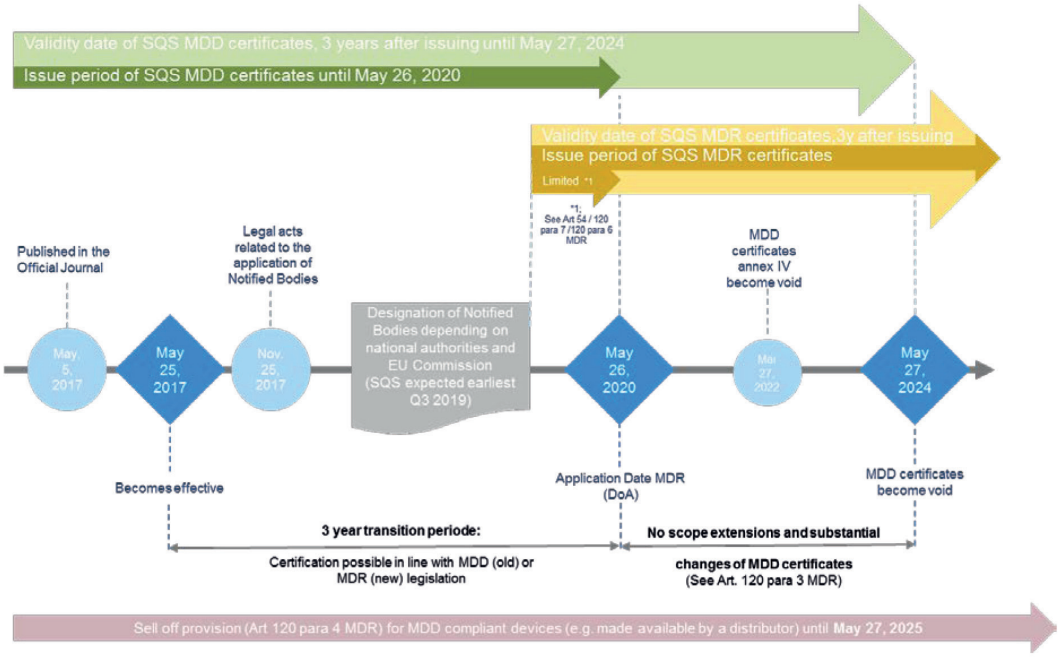
Swiss Association
for Quality and Management
Systems (SQS)

Medical Device Regulation 2017/745

MDR
Top 10 FAQ regarding the MDR

1. *How long can I place my product(s) on the market with my current MDD certificate?*

How long can I place my product(s) on the market with my current MDD certificate? The 3 year transition period was started May 25, 2017 and will end May 26, 2020 (=date of application (DoA)). During this period a certification is possible in line with MDD or MDR legislation. Consequently, May 26, 2020 is the last date a MDD certificate can be issued. Products can be placed on the market under the (old) Medical Device Directive as long as the corresponding certificate is valid, but no longer than May 27, 2024. To support you during this transition we established a transition roadmap providing more detail.



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2. *When will SQS issue the first MDR certificates?*

Designation of Notified Bodies is depending on national authorities and the EU Commission. SQS expects the Designation earliest in Q3 2019. We will keep you informed on this during the application period.

3. *Which MDR scopes is SQS planning to pursue?*

SQS plans to get designated for the scopes equivalent to the current maintained MD scopes to be able to serve all existing SQS customers.

4. *Which devices are covered with the new MDR?*

The new MDR covers all devices that have been previously addressed by the MDD for Medical Devices and the AIMD for Active Implantable Medical Devices. In addition products intended for “aesthetic” purposes (non-medical purpose) rather than medical purposes, such as colored contact lenses or cosmetic laser, will be covered as well by the new regulation. A list of these products can be found in appendix XVI of the MDR.

5. *What are the main changes the new MDR contains?*

- Stricter ex-ante control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- Improved transparency through the establishment of EUDAMED
- Introduction of an «implant card» containing information about implanted medical devices for a patient
- Reinforcement of the rules on clinical evidence
- Strengthening of post-market surveillance requirements for manufacturers, e.g. Annex III (Technical Documentation on post-market surveillance) has been added.
- Improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance

6. *What is EUDAMED?*

Eudamed is the European Database of medical devices. The functionality of EUDAMED cannot be guaranteed at the time of DoA. In the MDR the Commission is endorsing that the use of Eudamed is mandatory to manufacturers. Following information are included

- The electronic system on clinical investigations
- The electronic system on vigilance
- The electronic system regarding market surveillance

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7. What is the UDI (Unique Device Identification) System?

The Unique Device Identification (UDI) system is described in Annex VI and allows the identification and facilitates the traceability of devices. The UDI must be used for reporting serious incidents and field safety corrective actions. The manufacturer must keep up-to-date a list of all applied UDI as part of the technical documentation.
The UDI comprises the following

- A device identifier (DI) specific to a manufacturer and a device.
- A production identifier (PI) that identifies the produced device›s unit and if applicable the packaged devices

8. What is new regarding Medical Software?

A new software classification rule has been introduced (Annex VIII, Rule 11). In many cases, this regulation will lead to a higher classification requiring the involvement of notified bodies and the conduct of clinical trials.
In terms of compatibility, interoperability, verification and validation as well as UDI, the term software is explicitly named and specific requirements are set.

9. Do I need a «person responsible for regulatory compliance»?

Manufacturers shall have available within their organization at least one person responsible for regulatory compliance. The requisite expertise shall be demonstrated. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC shall have such person permanently and continuously at their disposal.

10. What does the MDR say about reuse of Medical Devices?

The reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device and should assume the obligations incumbent on manufacturers. Nevertheless, Member States should have the possibility of deciding that the obligations relating to reprocessing and re-use of single-use devices within a health institution or by an external reprocessor acting on its behalf may differ from the obligations on a manufacturer. The reprocessing and further use of single-use devices should only take place where permitted by national law.

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