Johner Institut

Fact Sheet MDR Transition Periods

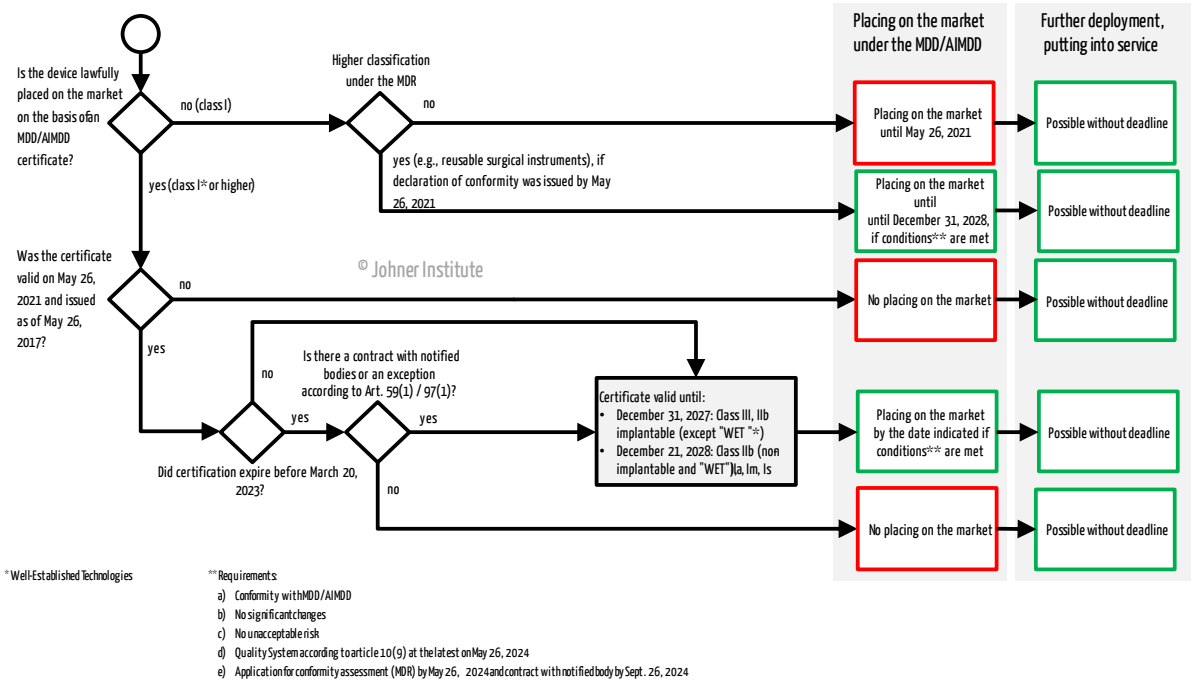
1. Overview

Aspect	Transition Period	Comment
MDR date of application	May 26, 2021	
Placing on the market of legacy devices	See flowchart below	
Making available of devices	There is no restriction	Since change 02/23
Putting into service devices	There is no restriction	Since change 02/23
OEM-PLM setup	The same transition periods apply to these devices.	As of May 26, 2021, the PLM must have the technical documentation in order to meet the MDR requirements for post-market surveillance and vigilance.
Person Responsible for Regulatory Compliance	See below	Restrictions regarding EUDAMED
Post-Market Surveillance	May 26, 2021	Restrictions regarding EUDAMED
Vigilance	May 26, 2021	Restrictions regarding EUDAMED
Quality System	For new devices and for the above-mentioned processes, such as PMS May 26, 2021	For devices already placed on the market, conformity with annex IX is not required during the transition period. Conformity with article 10 is required by May 2024 at the latest
UDI	See tab. below	
Clinical Investigations	May 26, 2021	Inspections that have been started may be continued, but new reporting requirements apply.

Article 10 of the MDR does not apply to devices benefiting from the transition period. Explicitly excluded from this are the above-mentioned requirements, including those for post-market surveillance and vigilance. In addition, the requirements of the article for the quality system must be fulfilled as of May 2024.

2. Placing on the market, making available, and putting into service

The length of time that manufacturers may continue to place their legacy devices on the market, make them available, and (allow them to be) put into service depends, among other things, on the class of the devices and the validity of possible certificates.



3. EUDAMED inclusive registration

Time	Duties
Up to 6 months after publication that EUDAMED is fully functional	–
From 6 months after publication	Registration of stakeholders, registration for clinical investigations, vigilance, PMS, registration of new MDR devices and certificates by notified bodies, and upload of SSCPs
Up to 12 months after publication	Completing the registration of legacy and MDR devices that were placed on the market before the 6 months after publication
Up to 18 months after publication	Completion of the registration of certificates by notified bodies and upload of SSCPs for devices that were placed on the market before the 6 months after publication

Special note for economic operators based in Germany: Separate transitional provisions apply to economic operators based in Germany. According to these, manufacturers and their Authorized Representatives must register directly in EUDAMED and not in the national BfArM database, DMIDS, from May 26, 2021. The same applies to importers of MDR-compliant medical devices.

4. UDI

The time at which the UDI carrier must be applied depends on the class of the device:

Class	Time
I	May 26, 2025
IIa	May 26, 2023
IIb	May 26, 2023
III and implantable devices	May 26, 2021

For reusable devices where the UDI carrier is to be placed on the device itself, the MDR grants two additional years.

Contact

The Johner Institute supports manufacturers in the transition to MDR:

- Consulting: An overview of possible forms of support can be found at https://www.johner-institute.com/.
  Our consulting services include:
  - Guidance on regulatory and clinical strategy
  - Reviewing documentation for MDR compliance
  - Improving documentation
  - Creation of technical documentation
  - Development of QM systems according to MDR
- Medical Device University (MDU): Over 250 video trainings show how to quickly place medical devices on the market in compliance with the law. A course originally developed for notified bodies provides tips on how to audit devices and organizations for MDR compliance.
- Templates: The MDU contains over 100 templates for product files and quality systems.
- Post-Market Radar: Automated information processing to always meet MDR requirements for post-market surveillance.

Would you like support? Do you have questions about the transition to MDR? The Johner Institute team is looking forward to hearing from you!

