MDR Dates of Application

26 May 2021: All devices, except those covered by the extended transition period, must comply with the MDR (e.g. class I, new devices, devices with a significant change).

26 May 2024: End of transition period for legacy devices that do not meet the conditions for application of the new transition periods (see conditions in red boxes below).

26 May 2026: End of derogation for class III custom-made implantable devices.

31 Dec 2027: End of transition period for class III and class IIb implantable devices (if not excepted, e.g. sutures).

31 Dec 2028: End of transition period for other class IIb, IIa, class I sterile/measuring devices, devices requiring notified body involvement for the first time under MDR.

Only devices covered by a notified body certificate or a manufacturer’s declaration of conformity issued before 26 May 2021 can potentially benefit from the extended transition period.

Conditions to be fulfilled to benefit from extended transition period:

- **26 May 2024**: Deadline to lodge an application for MDR conformity assessment & have an MDR QMS in place.
- **26 Sep 2024**: Deadline to sign a written agreement with an NB & transfer appropriate surveillance to an MDR NB (where applicable).
- **Devices continue to comply with previously applicable EU legislation (MDD/AIMDD)**.
- **No significant changes in design or intended purpose**.
- **Devices do not present an unacceptable risk to health or safety**.