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

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

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

***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