MDR transition timeline

26 May 2024

26 September 2024

26 May 2026

31 December 2027

31 December 2028

Manufacturers have implemented an MDR compliant QMS and have formally applied to a Notified Body

The Notified Body and the manufacturer have signed a formal written agreement Class III custom-made implantable legacy devices to be MDR certified

Class III and IIb implantable legacy devices (excluding WET) to be MDR certified Other Class IIb, Class IIa, Class Is and Class Im legacy devices to be MDR certified

Legacy devices
up-classified under
the MDR and now
requiring Notified
Body involvement, to
be MDR certified¹

All legacy devices must comply with the MDR²

Notes

- ¹ Only for legacy devices whose Declaration of Conformity (DoC) was signed by 26 May 2021 (e.g., Class Ir).
- ² The sell-off period has been removed. Legacy devices placed on the market before the end of the transition period can be made further available on the market without legal time restrictions.







