26 May 2026

Class III custom-made implantable legacy devices to be MDR certified

31 December 2028

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 NB involvement, to be MDR certified¹

All legacy devices must comply with the MDR²



The NB and the manufacturer have signed a formal written agreement

31 December 2027

Class III and IIb implantable legacy devices (excluding WET) to be MDR certified



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

