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

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

The NB and the manufacturer have signed a formal written agreement

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

Legacy devices up-classified under the MDR and now requiring NB involvement, to be MDR certified

All legacy devices must comply with the MDR

Only for legacy devices whose Declaration of Conformity (DoC) was signed by 26 May 2021 (e.g., Class Ir)

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