ACCESS TO EXTENDED MDR TRANSITION PERIOD

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)

End of derogation for class III custom-made implantable devices

End of the transition period for other class IIb, IIa, class I sterile / measuring devices, devices that need a notified body for the first time under MDR

26 May 2021	26 May 2024	26 May 2026	31 Dec 2027	31 Dec 2028
	End of the transition period for legacy devices that do not meet the conditions for application of the new transition periods		End of the transition period for class III & class IIb implantable devices (exceptions e.g. sutures)	

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

Check product portfolio → **MDR Certified ?** → **Extension granted ?** → **Watch for next deadlines**

check your portfolio now !

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY