

IVDR transition timeline

	IVDR compliant QMS	Formal application lodged	Formal written agreement with a Notified Body signed	Transition deadline
IVDD certified devices ¹	26 May 2025	26 May 2025	26 September 2025	31 December 2027
Class D self-declared ²				
Class C self-declared ²		26 May 2026	26 September 2026	31 December 2028
Class B and A ² Sterile self-declared		26 May 2027	26 September 2027	31 December 2029

Notes

¹ **IVDD certified devices:** IVDD Certification from a Notified Body.

² **IVDD self-declared devices:** IVDs on the market under IVDD that did not need a Notified Body Certification.

The sell-off period for self-certified IVDs already placed on the market under the IVDD has been removed. These devices can be made further available on the market without legal time restrictions. For in-house devices, the requirement to justify that an equivalent device is not available on the market is postponed until May 2028.

