

Only devices that are covered by a notified body certificate issued under the IVDD or that did not require the involvement of a notified body under the IVDD but do so under the IVDR can potentially benefit from the extended transition periods

26 May 2022

All devices, except those covered by the transition period, must comply with the IVDR (e.g. class A non-sterile devices, new devices, devices with a significant change)

26 May 2025

End of transition period for class D devices and for devices with a certificate issued by a notified body under the IVDD (e.g. devices for self-testing)



End of transition period for class C devices



End of transition period for class B devices and class A sterile devices

Conditions to be fulfilled to benefit from extended transition period



Devices continue to comply with previously applicable EU legislation (IVDD)



No significant changes in design or intended purpose



Notified body certificate or declaration of conformity drawn up before 26 May 2022