IVDs concerned	Original Regulation Text	Amended text
Devices with a Notified Body certificate under the IVDD and requiring an NB assessment under the IVDR • IVDD Annex II List A & B • Self-tests	27 May 2022	Extend transition period until: **26 May 2025**
Devices with a Declaration of Conformity (DoC) under the IVDD and requiring NB involvement under the IVDR	27 May 2022	Extend transition period on a risk-based approach: • Class D: until **26 May 2025** • Class C: until **26 May 2026** • Class B and A sterile: until **26 May 2027**
In-house devices: deferred application of the requirements for devices manufactured and used within the same health institution	27 May 2022 (b) manufacture and use of the devices occur under appropriate quality management systems; (c) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation; (e) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use; (f) the health institution draws up a declaration which it shall make publicly available, including: (i) the name and address of the manufacturing health institution, (d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;	In Article 113(3) two points on In-house devices are added: • (i) Article 5(5), points (b), (c) and (e) to (i), shall apply **from 26 May 2024** • (j) Article 5(5), point (d), shall apply **from 26 May 2028**