

Timeline Regulation (EU) 2017/746 (IVDR)

in consideration of
 Regulation (EU) 2022/112
[Regulation \(EU\) 2024/1860](#)
 & [Q&A on practical aspects](#)

Requirements acc. to VO (EU) 2024/1860:

- Compliance of the products acc. to Directive 98/79/EC
- No significant changes of the products (MDCG 2022-06)
- No "unacceptable risks to health and safety"
- Establishment of a QMS in accordance with Article 10(8) of the IVDR until 26 May 2025
- Implementation of the requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices
- Formal application in accordance with Annex VII, Section 4.3, of the IVDR for conformity assessment in respect of the "legacy device" timely per product classification
- Written agreement between the manufacturer and the NB within four months thereafter

