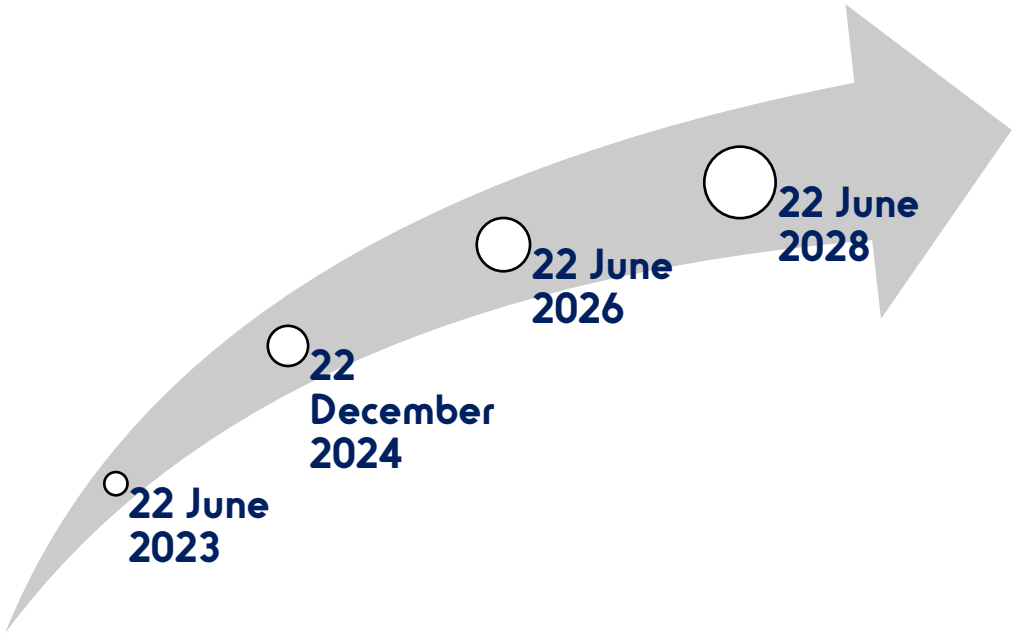
Commission Implementing Regulation (EU) 2022/2346 Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down *common specifications for the groups of products without an intended medical purpose listed in Annex XVI* to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

Transitional provisions (Art. 2)

A product for which the manufacturer intends to perform, or is performing, a clinical investigation

Devices already on the market prior to June 2023 + no significant changes in design & intended purpose

- **From 22 June 2024 until 22 December 2024**: a product may only be placed on the market or put into service, if the sponsor has received from the Member State concerned a **confirmation that the application for the clinical investigation of the product is complete**
- **From 23 December 2024 until 22 June 2026**: a product may only be placed on the market or put into service, **if the sponsor has started the clinical investigation**.
- **From 23 June 2026 until 22 June 2028**: a product may only be placed on the market or put into service, if **a written agreement for the performance of the conformity assessment has been signed** by the notified body and the manufacturer.
- **22 June 2028 and onwards**: All products of Annex XVI must comply with EU Regulation 2017/745

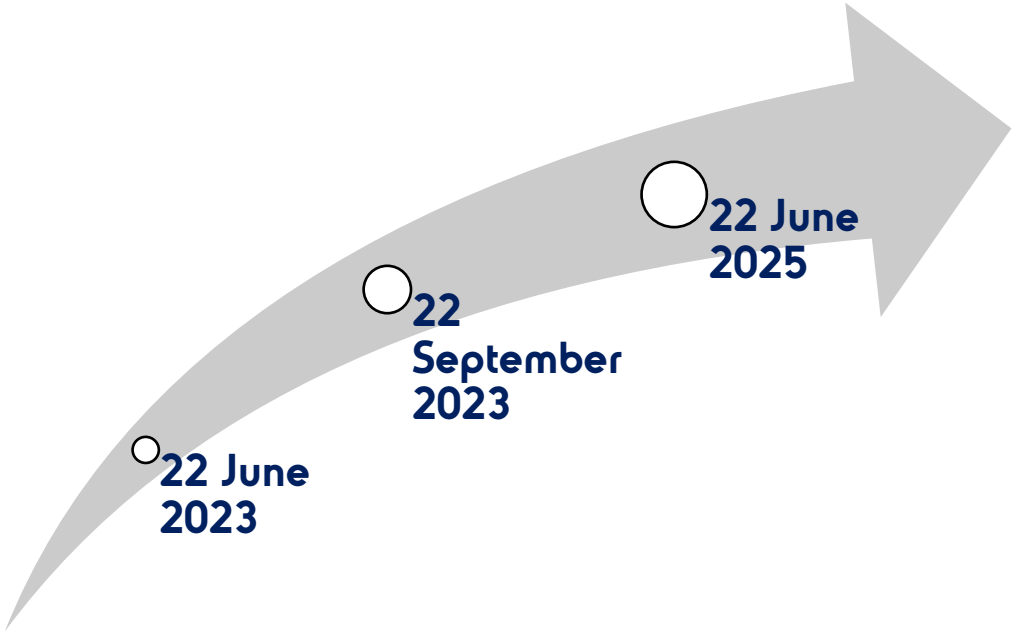


We provide measurable actions and tailored solutions.
Let us be the bridge between your operational reality and current regulatory expectations.

A product for which the manufacturer does not intend to perform a clinical investigation

Devices already on the market prior to June 2023 + no significant changes in design & intended purpose

- **From 22 September 2023 until 22 June 2025**: a product that meets the conditions may only be placed on the market or put into service, if a **written agreement for the performance of the conformity assessment has been signed by the** notified body and the manufacturer.
- **22 June 2025 and onwards**: All products of Annex XVI must comply with EU Regulation 2017/745



A product covered by a certificate issued by a notified body in accordance with MDD

Devices already on the market prior to June 2023 + no significant changes in design & intended purpose

- **A product may be placed on the market or put into service until**
  - **22 June 2025** if there are no plans to conduct a clinical investigation
  - **22 June 2028**: if a clinical investigation is planned and all corresponding milestones have been achieved

➢ After the expiry date of the MDD certificate, the appropriate surveillance of
  - ✓ The compliance with MDD requirements
  - ✓ The fact that there are changes in the design + intended purpose

is ensured by a written agreement signed by the notified body that has issued the MDD certificate or a notified body designated in accordance with MDR and the manufacturer.

- **22 June 2028 and onwards**: All products of Annex XVI must comply with EU Regulation 2017/745