

ANNEXES

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General safety and performance requirements

- II Technical documentation
- III Technical documentation on post-market surveillance
- IV EU declaration of conformity
- V CE marking of conformity
- VI Information to be submitted upon the registration of devices and economic operators in accordance with Articles 29(4) and 31; core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 28 and 29; and the UDI system
- VII Requirements to be met by notified bodies
- VIII Classification rules
- IX Conformity assessment based on a quality management system and assessment of the technical documentation
- X Conformity assessment based on type examination
- XI Conformity assessment based on product conformity verification
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- XIII Procedure for custom-made devices
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