

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 26(3) and 28, core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 25 and 26 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 on assessment of technical documentation

X Conformity assessment based on type examination

XI Conformity assessment based on production quality assurance

XII Certificates issued by a notified body

XIII Performance evaluation, performance studies and post-market performance follow-up

XIV Interventional clinical performance studies and certain other performance studies

XV Correlation table