MDR Conformity Assessment Procedure CLASS III

MEDCERT
Certification. Medical Only.

Annex I	General Safety and Performance Requirements
Annex II	Technical Documentation
Annex III	Technical Documentation on Post Market Surveillance
Annex IV	EU Declaration of Conformity
Annex VI	UDI – Unique Device Identification
Annex VIII	Classification Rules

Annex X *
Type Examination

Annex IX
Technical Documentation
Quality Management System
(EN ISO 13485)

III implantable
III medicinal
III human origin
III animal origin
III absorbed/dispersed

Annex XI, Part A
Production Quality Assurance
(EN ISO 13485)

Annex XI, Part B *
Product Verification

Annex IX, Section 5
Specific Additional Procedures

CE 0482

*This service is not offered by MEDCERT, and the marking "CE 0482" may not be affixed under this annex.