



Medical Device Conformity Assessment Routes

In order to demonstrate compliance with the essential requirements, the manufacturer must follow the conformity assessment procedure appropriate for the medical device concerned.

The number of the applicable annexes varies between the three Directives, and the following table may serve as a useful guide:

	AIMD	MDD	IVDD
Full Quality Assurance	2	II	IV
EC Type Examination	3	III	V
EC Verification (Type Test of every batch)	4	IV	VI
Production Quality Assurance (ISO 13485 without Design)	5	V	VII
Inspection Quality Assurance (ISO 13485 without Design and Manufacture)		VI	
EC Declaration of conformity		VII	III