Understanding the Medical Devices Directive

NEW DEVICE

Determine class using Annex IX classification rules

Ensure the device meets the ‘Essential Requirements’ in Annex I which apply to it, taking into account its intended purpose

Increasing level of potential risk associated with the use of the medical device

Class I

Annex VII: prepare technical documentation

Is the device sterile or have a measuring function?

YES

NO

Class IIA

Annex VII: prepare technical documentation

Class IIB

Annex III: prepare technical documentation & submit with product to a NB for type examination

NB issue an EC type examination certificate

OR

OR

OR

If sterile, also apply Annex V section 3 & 4 on aspects of manufacturing that secure & maintain sterility

Annex IV examination & verification of every device/batch by a NB

Annex V audit of production QA system by a NB, to ISO 13485 (excluding design)

Annex VI audit of final inspection & testing QA system by a NB, to ISO 13485 (excluding design & manufacture)

Register device with the Competent Authority (Form RG2)

Compile self declaration of conformity & apply CE mark

Compile declaration of conformity & apply CE mark with NB registration number

NB issue certificate(s) of conformance for the device

MARKET THE DEVICE

Maintain Post Market Surveillance, taking corrective action where required (vigilance) (To identify problems or risk, maintain safety of the product in the field and notify the Competent Authority of any serious adverse incidents)
Medical Devices Directive

Conformity Assessment Routes

It is illegal to sell a medical device that does not have a CE mark and meets the requirements of the Medical Devices Directive. This diagram is a simplified interpretation of the conformity assessment routes that a manufacturer must follow in order to comply with the Directive.

Notes:
- NB = Notified Body
- Blue tinted boxes indicate that a Notified Body is directly involved in the process by either the analysis of technical documentation and product, or an audit of the manufacturing facility
- This diagram is Robinson Healthcare’s interpretation of information contained within the Medical Devices Directive. The Directive should be consulted in order to clarify any aspect of this interpretation.