Europe's regulatory process for medical devices

Determine the CLASSIFICATION of your device using Annex VIII of the Medical Devices Directive (MDR). All active implantable medical devices are Class III.

(Non-sterile) Class I (Non-measuring)	(Sterile) Class I (Measuring)	Class IIa	Class IIb	Class III

Implement QUALITY MANAGEMENT SYSTEM (QMS) in accordance with MDR Most companies apply the ISO 13485 standard to achieve QMS compliance

Prepare a DECLARATION OF CONFORMITY, a legally binding document prepared by the manufacturer stating that the device is in compliance with the applicable Regulation. You may now affix the CE Marking

Appoint an AUTHORIZED REPRESENTATIVE (EC REP) located in Europe and qualified to handle regulatory issues Place EC REP name and address on packaging

Register the manufacturer and the medical device in the EUDAMED database As a result you will get the unique device identifier (UDI)

Your QMS & Technical File or DESIGN DOSSIER must be audited by a Notified Body** A CE Certificate*** for your Device will be issued upon successful completion of the Notified Body Audit.

Prepare a TECHNICAL FILE which provides detailed information demonstrating compliance with the Medical Devicves Regulation EC 2017/745*

*Class III devices as well as active implantable devices will likely require substantial clinical trial data. Clinical trials conducted in Europe must be pre-approved by a Competent Authority. Existing clinical data may be acceptable. All data are reviewed and approved by a Notified Body.

**Notified Body = EU accredited third party authorized to conduct audits of medical device companies and their devices.

***A CE Certificate (issued by a Notified Body) is not applicable to Class I, non-sterile, non-measuring devices since manufacturers will self-declare conformity with the Regulation EC 2017/745.