

Road to CE-marking in 8 Steps:

- 1 **Applicable legislation**
Which legislation is applicable to the product:
 - Medical Devices Directive (MDD, 93/42/EC)
 - Active Implantable Medical Devices Directive (AIMD, 90/385/EEC)
 - In Vitro Diagnostics Medical Devices Directive (IVD, 98/79/EC)
 - Tissue of animal origin Directive (2003/32/EC)
- 2 **Product Classification**
A product needs to be classified according the applicable legislation.
- 3 **Conformity assessment**
Depending on the classification of the product the proper procedure shall be chosen and followed in order to affix the CE-marking.
- 4 **CE-marking**
A device has to bear the CE-marking in order to be sold within the European Union. The CE-mark presumes that the essential requirements for the applicable device for the concerning directive are met.
- 5 **Technical files/ Design Dossier**
Detailed information to demonstrate compliance with all the requirements in the concerning Directive.
- 6 **Authorized Representation for Europe**
An authorized representative with a physical office in the European Union needs to be appointed to handle defined regulatory matters to represent the foreign manufacturer to Notified Bodies, Competent Authorities and other regulatory authorities
- 7 **Post marketing surveillance / Vigilance reporting**
All activities regarding complaint handling and the evaluation and notification of adverse events.
- 8 **Clinical Evidence**
All activities for the necessary clinical evidence for the device.