i3 Consulting

WE QUALIFY YOU

Your Guide for European compliance

We Specializes in

Low, Medium and High-risk medical devices which requiring Design Dossier Reviews and Quality Management System are all our specialization. Our technical competency and our advanced level of skill are known from our certified client's worldwide.

- Vascular
- Orthopedic
- Active Implantable
- Medical Software
- Electro-Medical
- Blood and Animal Tissue
- Invasive and Surgical
- Wound Care
- Dental
- Medicinal Substances
- Ophthalmic

Why Consultant is required for CE Marking of your Medical Devices

- Technical consultant for ISO 13485 & CE approval.
- Identifying all EU Directives applicable to your product.
- Classification of medical device.
- Implementing medical device quality management system.
- Selecting the most appropriate conformity assessment module.
- Risk analysis as per ISO 14971:2009.
- Identify the Harmonized Standards applicable to your product.
- Selecting suitable testing Laboratory.
- Identify whether assessment of your conformity is required by a Notified Body.
- Selection of Notified Body.
- Maintain Technical Documentation required by the Directive(s).
- Preparing the "Technical File".
- Label Review.
- Prepare the Declaration of Conformity
- Arranging the EU Authorized Representative.
- Co coordinating with auditors.
- Affix CE mark on your product and/or packaging.
- Annual maintenance contract.

Request Proposal