CE Marking and Technical File Compilation

Qserve provides support to medical device companies that are seeking CE regulatory approval for their products in Europe. Qserve's consultants have a wealth of experience in the preparation of regulatory submissions required to obtain CE marketing clearance and have built strong relationships with the Notified Bodies. Qserve can help you bring your product to the market faster, minimizing the time and costs involved, and maximizing your product revenues.

"CE Mark" means that the product is safe and fit for the purpose for which it was made. Medical Devices Directives (MDD) specify requirements which must be met before permission is granted to apply the CE marking to your medical device and placing it on the market. The Directives which apply to medical devices are:

- **Active Implantable Medical Device Directive (90/385/EEC)**

This directive covers all medical devices, which rely on a power supply to function and that are left in the human body. These include implantable cardiac pacemakers, implantable nerve stimulators, etc.

- **Medical Device Directive (93/42/EEC)**

The Medical Device Directive covers most other medical devices (active and non-active) and their accessories that are not covered by the first or the third directive. This concerns a large number of products ranging from walking aids to prosthetic heart valves.

- **In Vitro Diagnostic Medical Device Directive (98/79/EC)**

The In Vitro Diagnostic Medical Device Directive will cover any reagent, reagent product, control material, kit, medical device, instrument, apparatus or system which is intended to be used in-vitro for the examination of substances derived from the human body.

Qserve has helped many companies bring their products, including high risk, border line and/or combination devices, successfully and efficiently to market within the EU, and we can help you with your products, no matter what their classification,

Qserve is able to provide coordinated advice on European, US and worldwide strategic regulatory and quality affairs, minimizing your costs. If required, we can represent your company to national and international authorities. Our range of services includes:

- CE Marking
- Selection of the appropriate Notified Body
- Device Classification & Conformity Route Assessment
- GAP Analysis (a first assessment to verify what is needed)
- Preparation, review and submission of CE Technical file(s) and CE Design Dossier(s)
- Management regulatory studies (e.g. pre-clinical testing, shelf-life, labeling, packaging and sterilization)
- Design and Risk Analysis and Risk Management (ISO 14971)
- Advice on the Essential Requirement(s) and Labeling and Language compliance
- Advice on of a Complaint, Recall, Vigilance and Post Market Surveillance System
- Design control and manufacturing support & documentation
- Expert scientific reports and other technical documentation
- Implementation and Maintenance of Quality Management Systems (ISO 13485)
- Experienced Consultants, who work closely with you, to ensure timely and on budget implementation of the QMS

If you would like more information, or a free consultation and price quotation, please contact us.