Cardiovascular Medical Devices
Assessing the Safety of Cardiovascular Medical Devices

Further, given the greater degree of risk that they pose to patients, cardiovascular devices are also subject to significant review and oversight by medical device regulators in most major jurisdictions. In the EU, for example, implantable cardiovascular devices, which are regulated under the EU Directive on medical devices (93/42/EEC), will soon be expected to meet the more stringent requirements of the new EU medical device regulation (MDR).

The expected changes include the reclassification of certain cardiovascular medical devices used in contact with the heart or the central circulatory system, more rigorous requirements for clinical evaluations and investigations, post-market surveillance and an increased scrutiny from national authorities and EU commission in the pre-market and post-market phases”.

For manufacturers of cardiovascular devices, overcoming these and other challenges require both in-depth technical knowledge and extensive regulatory experience.
These challenges can be especially daunting for small and medium-sized companies, who constitute the majority of medical device manufacturers.

**How can we help you?**

TÜV SÜD is the world’s largest EU Notified Body for the full scope of medical devices covered by the relevant EU directives and regulations. We are also a leading global management certification body for quality management systems, including management systems applicable to the manufacture of medical devices. This unique combination of experience makes TÜV SÜD ideally suited to address the needs of medical device manufacturers seeking to achieve or maintain compliance with medical device requirements in the EU and other major markets around the world.

TÜV SÜD bases its success in the cardiovascular field on the vast technical, clinical and regulatory expertise of the staff. Over twenty experts are dedicated to high risk cardiovascular devices, with expertise ranging from the technical to the clinical aspects and in specific fields covering tissue of animal and human origin, absorbable devices and medicinal substances.

As predictability is paramount for our customers, our team of project managers provide assistance and support on all activities covering conformity assessment, ensuring resources are used efficiently and project timelines are scrupulously met.

TÜV SÜD’s services for cardiovascular and other high risk medical devices include:

- **Technical documentation review** - TÜV SÜD reviews the technical documentation for the device according to the requirements applicable to high risk devices, and issues the required product certificate following the completion of a positive assessment. The reviews are conducted by specialists with vast experience in the specific cardiovascular devices.

- **Quality system auditing** – TÜV SÜD performs a quality system audit consistent with regulatory requirements, and can issue a Quality Management System certificate following the completion of a positive assessment.
Testing services – TÜV SÜD provides compliance testing for high risk implantable medical devices in accordance with relevant regulations and standards. Assessments are based on witness testing conducted on the applicant’s premises.

Clinical services – TÜV SÜD Clinical Centre of Excellence comprises a number of clinicians trained on medical devices regulations and fully dedicated to clinical reviews. The unrivalled in-house clinical expertise covers the areas of heart surgery, interventional cardiology, electrophysiology, neurovascular surgery and many others. The direct access to the clinical reviewers allows TÜV SÜD to offer high quality and fast clinical reviews, that can be tailored to the specific product or customer needs.

Market approvals and certification – The regulatory requirements are often complex and vary between regions. TÜV SÜD has in-depth knowledge and experience of the key medical device markets around the globe to help you navigate the regulatory requirements and obtain the necessary approvals for your medical devices.

Your benefits

- Recognized medical device expertise - TÜV SÜD is the largest EU Notified Body in the world. With a Regulatory Foreign Affairs and an in-house Clinical Centre of Excellence, TÜV SÜD is recognised by global regulatory authorities for its extensive experience with all types of medical devices.

- Predictability – TÜV SÜD understands how predictability is key for the successful development and placement of a medical device on the market. That is why we offer clear timelines that can be tailored to the specific project needs and employ project managers dedicated to guarantee timelines are successfully met.

- Active involvement in standards development and implementation – TÜV SÜD technical professionals are actively involved in standards development activities related to all types of medical devices, and participate in key standards committees. TÜV SÜD Product Service is also a member of Team NB, the European Association for Medical Devices of Notified Bodies, which facilitates the exchange of information on medical device standards and regulations.
• **Single source solution** – TÜV SÜD offers a full range of review and testing services for high-risk medical devices as required by regulators in the EU, the U.S. and other major medical markets around the world.

• **Expert partnership** – TÜV SÜD is a trusted partner to companies ranging from global manufacturers to regional and local start-up companies.

### Why choose TÜV SÜD?

TÜV SÜD offers a complete range of testing, certification and auditing services to manufacturers of medical devices, including high risk implantable devices, helping them to manage risks and to protect and promote the health and safety of patients. Our global network of more than 500 dedicated medical health and services professionals include noted scientists and physicians recognised as authorities in their respective fields. These capabilities make TÜV SÜD the preferred single source for worldwide compliance with medical device regulations.

Represented in over 1,000 locations worldwide, TÜV SÜD has an unsurpassed track record of meeting expectations of our client companies. The TÜV SÜD brand and our distinctive blue octagon mark are instantly recognised around the globe as symbols of quality and safety, and will increase customer confidence in your brand.

### Related services

TÜV SÜD provides the following related services:

- Global approval of medical devices (foreign affairs)
- ISO 9001 – Quality management system certification
- ISO 13485 – Quality management system certification for medical devices
- Medical device market assessment
- Testing and certification for regulatory approval