Add value.
Inspire trust.

Design dossiers for high-risk medical devices

Reduce time to market with competent, predictable review services customised to your needs.

Your challenges

The failure of high-risk (class III) medical devices can result in lawsuits, product recalls and, in worst-case scenarios, serious injury or death to patients. For these reasons, regulations governing high-risk products are becoming stricter and more complex every year, leading to extensive assessment processes and greater scrutiny by users and authorities. The lengthy design dossier review period can seriously hamper a manufacturer's speed to market. Manufacturers also risk having their design dossiers rejected, which may result in expensive product redesign and having to repeat the long review process.

What is a design dossier?

Design dossiers are extensive technical documents that demonstrate a manufacturer's product meets the requirements of relevant regulations. They include test reports, risk management reports, assessments of clinical evaluations, biological evaluations and other reports that need to be reviewed by a Notified Body before they may be approved.

Why are design dossier reviews important for your business?

Design dossier reviews and certifications are required for CE marking of high-risk devices according to the Active Implantable Medical Device Directive 90/385/EEC, Medical Device Directive 93/42/EEC and In-Vitro Diagnostics Directive 98/79/EC. Having a reputable Notified Body review your design dossier can improve the confidence of regulatory authorities in your product and curtail risks of legal liability, product recalls or harm to patients.

Design dossier review expertise from TÜV SÜD

TÜV SÜD undertakes the required design dossier reviews and issues design examination certificates in accordance with the three Medical Device Directives. As the only Notified Body with our own team of medical doctors and capability to review assessments of clinical evaluations for all medical devices, we assess high-risk devices with animal and human origin components as well as drug/device combination products and devices using innovative technologies. In each case, we prepare a

detailed evaluation report assessing the risk analysis, risk management strategy, performance, biocompatibility and sterility, etc., including specific aspects when applicable, e.g. the methods applied for inactivation of transmissible spongiform encephalopathy (TSE).

Our design dossier review and other high-risk medical device services

- **Competent design dossier reviews**
  TÜV SÜD can review your design dossier and issue design examination certificates in accordance with the three mentioned Medical Device Directives.
- **Expedited services**
  We provide you with tailored services that cater to your business needs, with express design dossier review services for when you need to accelerate your time to market.
- **Testing**
  TÜV SÜD's global network of accredited test laboratories is among the most sophisticated in the world. Among others services, we offer testing and certification for electrical safety, performance, biocompatibility and electromagnetic compatibility.
- **Medical pre-review**
  Our team of in-house medical doctors conduct a pre-review of your clinical documentation, even if other parts of the design dossier are not yet completely finished, and identify possible regulatory hurdles.
- **Regulatory quality management system audits**
  Besides conducting audits, TÜV SÜD's experts' findings and explanations allow you to improve the safety, quality, effectiveness and reliability of your product.
- **Scientific review / evaluation meetings**
  Plan a foolproof regulatory strategy by leveraging the expertise and knowledge of TÜV SÜD's doctors, scientists and regulatory experts.

Your business benefits

- **Increase speed to market** – with solutions that result in quicker product development, smoother product testing and faster market launches.
- **Gain a competitive edge** – by leveraging the world-renowned reputation of the TÜV SÜD certification mark.
- **Benefit from global services** – with experienced engineers in your local markets that speak your language.

Why choose TÜV SÜD?

Renowned for being independent and impartial, TÜV SÜD is the world's largest Notified Body in the medical devices industry. With more than 400 dedicated medical health and services experts around the globe, we employ our own medical doctors for assessing the evaluation of your new treatment methods and systems, and have our own scientific advisory board manned by scientists from world-class universities. TÜV SÜD has voluntarily signed a Code of Conduct for Medical Device Notified Bodies to improve the harmonised implementation of European Directives, allowing our experts to gather crucial insights to provide clients with unrivalled knowledge and foresight. Our experts sit on numerous medical device standards development committees around the world. We also have a Regulatory Foreign Affairs & Clinical Department specialising in market access and worldwide regulations.

Add value. Inspire trust.

TÜV SÜD is a premium quality, safety and sustainability solutions provider that specialises in testing, inspection, auditing, certification, training and knowledge services. Represented in over 800 locations worldwide, we hold accreditations in Europe, the Americas, the Middle East, Asia and Africa. By delivering objective solutions to our customers, we add tangible value to businesses, consumers and the environment.

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 and certification
- Medical device testing

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