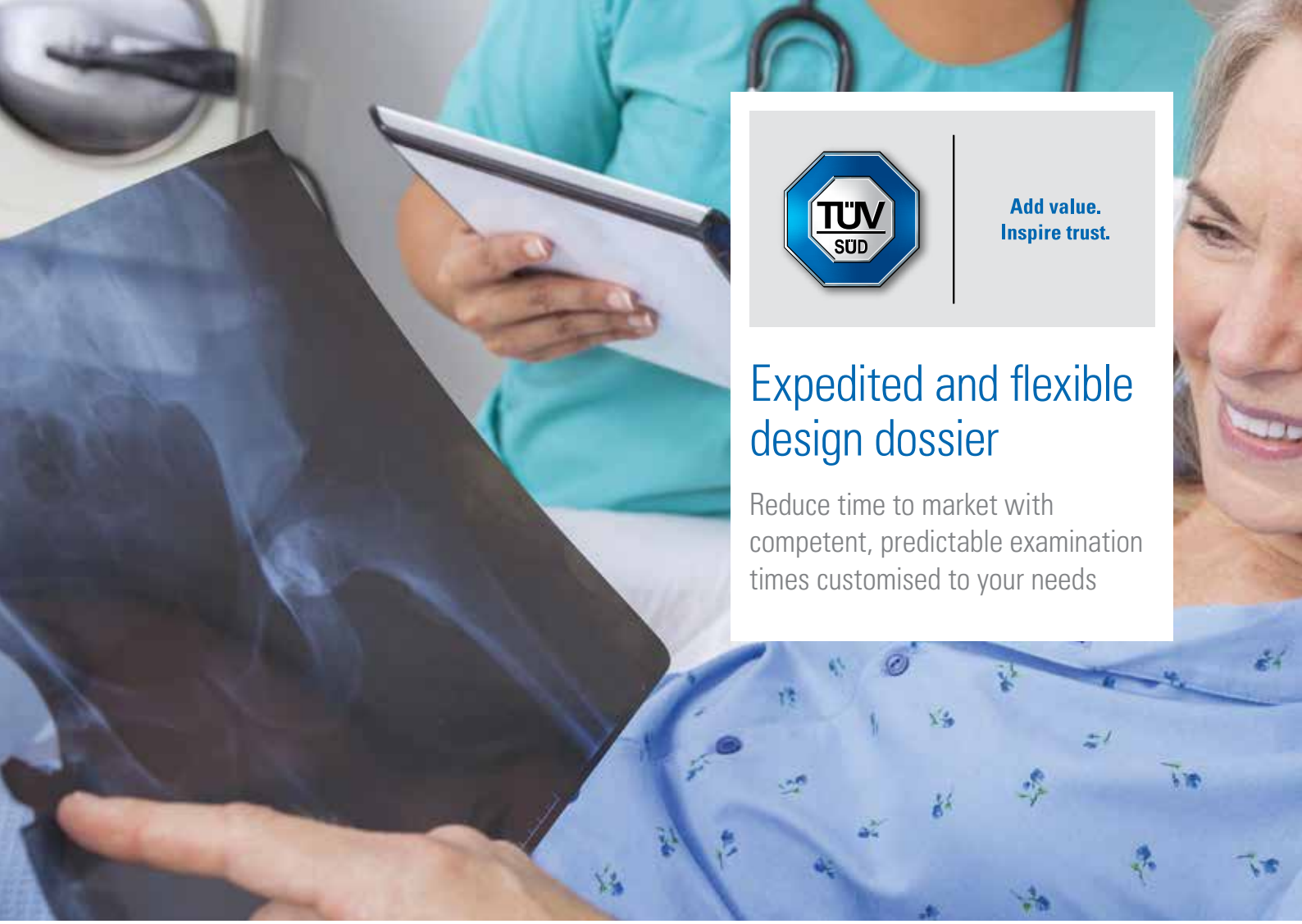


Add value.
Inspire trust.

Expedited and flexible design dossier

Reduce time to market with competent, predictable examination times 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, leading to extensive assessment processes and greater scrutiny by users and authorities. The lengthy design dossier examination 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 examination process.

What is a design dossier?

Design dossiers are extensive technical documents which demonstrate that a manufacturer's product meets the requirements of the Medical Device Directive 93/42/EEC, along with two associated Directives, the Active Implantable Medical Device Directive 90/385/EEC and the In-Vitro Diagnostics Directive 98/79/EC, which together cover all medical equipment. Dossiers must include test reports, risk management reports, assessments of clinical evaluations, biological evaluations and other reports, and need to be examined by a Notified Body before they may be approved. Having a reputable Notified Body examine your design dossier means you can be confident that your documentation is fully examined against the necessary regulatory requirements.

Design dossier examination expertise from TÜV SÜD

TÜV SÜD undertakes the required design dossier examinations and issues design examination certificates in accordance with the three Directives.

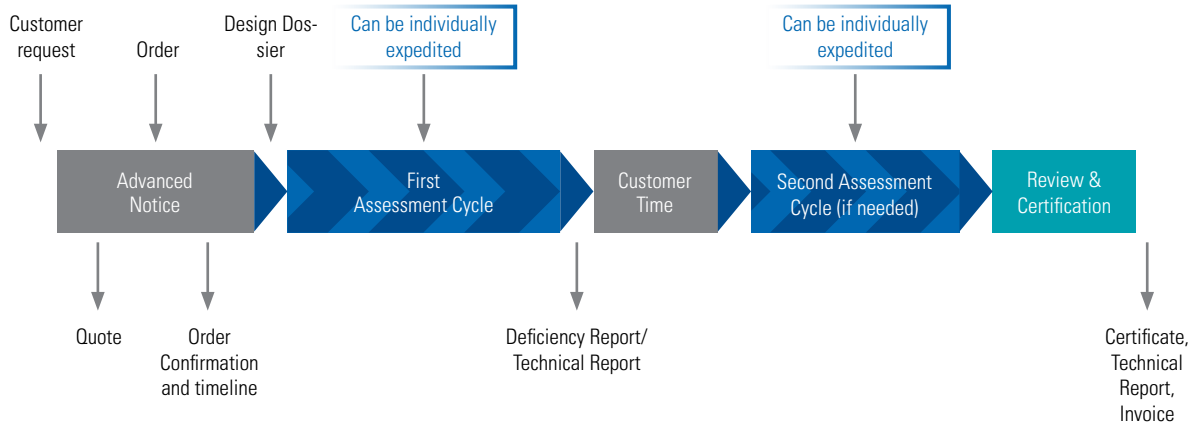
As a Notified Body with our own team of medical doctors and the largest team of experienced clinical reviewers, we have the capability to examine assessments of clinical evaluations for all medical devices including high-risk devices with animal and human origin components, drug/device combination products and devices using innovative technologies. In each case, we prepare a detailed

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

TÜV SÜD design dossier examination services

- **Competent design dossier examinations**
  TÜV SÜD can examine your design dossier and issue product certificates in accordance with the three Directives - Medical Device Directive 93/42/EEC, Active Implantable Medical Device Directive 90/385/EEC and In-Vitro Diagnostics Directive 98/79 EC.
- **Expedited and flexible services**
  We provide you with tailored services that cater to your business needs. This includes expedited design dossier examination services, which reduces the examination period when you need to accelerate your time to market. While this means a prioritisation of the project, it does not guarantee certification, as this is also dependent on the quality of the submitted documentation. In the event that you would like to choose the expedited and flexible service, please inform us as soon as possible.

TÜV SÜD DESIGN DOSSIER EXAMINATION PROCESS



Streamline your submission to TÜV SÜD

To improve the predictability and efficiency of TÜV SÜD's examinations, you should submit a completed EC application eight weeks prior to the submission of your design dossier or change notification. The completed application should include all required annexes from www.tuv-sud.com/medicaldevice/forms.

Additional information is also required for:

- **Registration of new devices:**
  - A draft of the instructions for use and/or a product description.
- **Innovative and/or borderline products:**
  - The justification of the product's classification as a medical device, including the classification rules.
  - A list of all components and their concentrations.
  - In the case of combination products, this must include the benefits of the drug component.

Certification extensions has to be applied a minimum of six months prior to the expiry of your certificate.

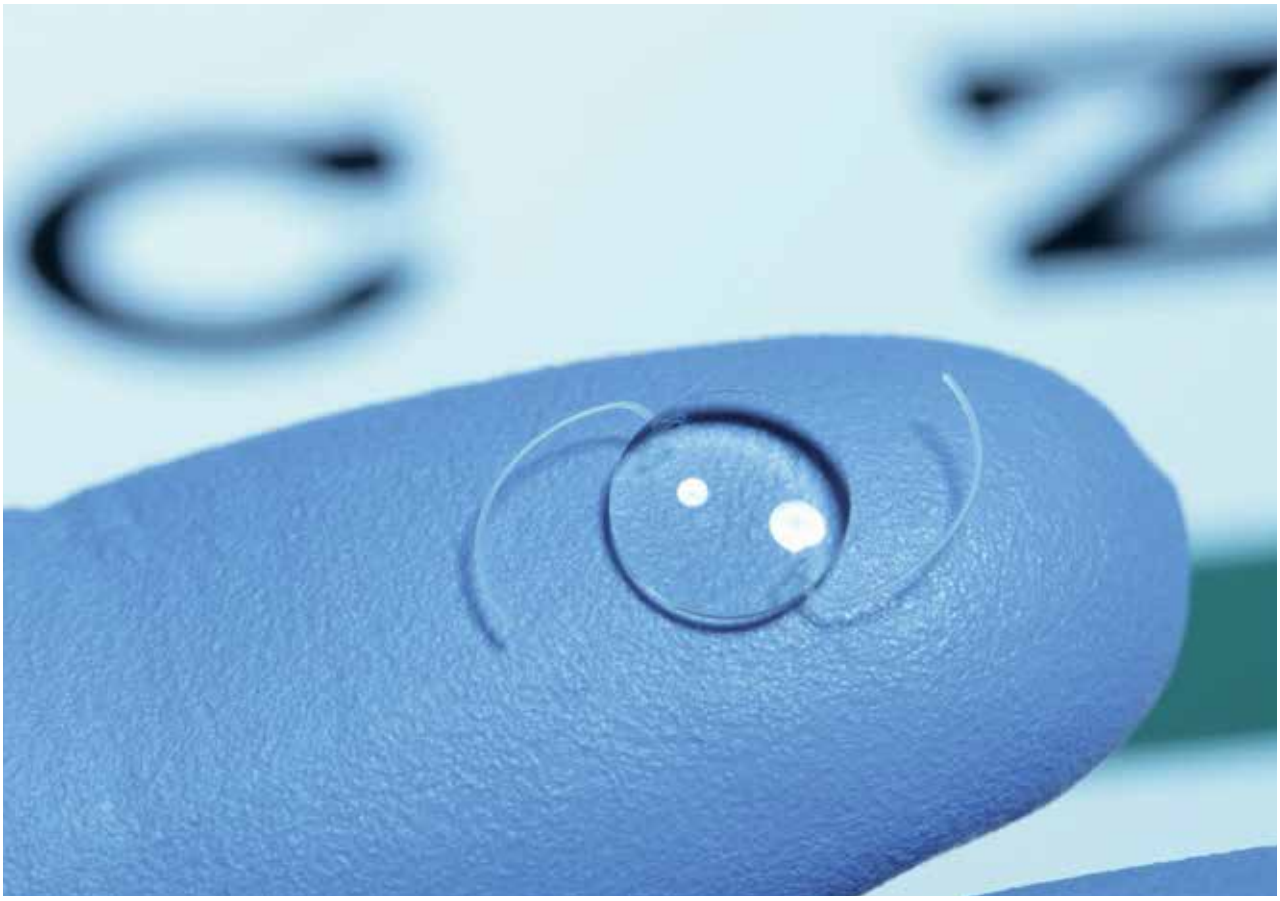
The extension application should include a complete and updated design dossier in accordance with the requirements of Medical Device Directives.

Please submit your complete technical documentation file (preferably in STED-format as a searchable PDF) to your local office, to nam-DD@tuev-sued.de, or to the following address below.

TÜV SÜD Product Service GmbH
MHS/NAM-DD Assistant's Office
Ridlerstrasse 65
80339 Munich
Germany

Examination timeline

Once your written order, and all required documents have been submitted, our order confirmation will state the proposed start date. Provided that no unexpected difficulties occur, the duration of the examination (including certification) is approximately 90 working days including one additional round of questions and answers. You will



receive a first response regarding your design dossier assessment typically after 40 working days. Alternatively, we can offer individual expedited and flexible services. This service also applies for Change Notifications in Design Dossiers and Certificate Extensions. For certificate extension, it is recommended that the project commences at least six months prior to the expiry date.

Your business benefits

- **Increase speed to market** – with solutions that result in smoother document examination and faster market launches.
- **Gain a competitive edge** – by leveraging the world renowned reputation of TÜV SÜD certification.
- **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 one of the world's largest Notified Body in the medical devices industry. With over 700 dedicated Medical Health Services experts around the globe, we 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 and Clinical Centre of Excellence specialising in market access and worldwide regulations.

Add value. Inspire trust.

TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specialises in testing, certification, auditing and advisory services. Through more than 24,000 employees across over 1,000 locations, the company adds value to customers and partners by enabling market access and managing risks. By anticipating technological developments and facilitating change, TÜV SÜD inspires trust in a physical and digital world to create a safer and more sustainable future.

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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