Add value.
Inspire trust.

# Transfer to TÜV SÜD, the Notified Body of choice

Achieve more success with a partner that adds value to your business

## Your challenges

The medical device manufacturing sector will soon face more stringent requirements with the new Medical Device Regulation (MDR). Manufacturers might be challenged to source for a new Notified Body (NB) in order to comply with the new regulation. It is crucial to select a NB that offers a complete suite of solutions and ensures timely delivery. In no small part, success depends on the reliability and competence of the manufacturer's testing and certification partner.

## Why change your Notified Body?

Choosing the right NB can improve your business performance and operations while reducing your exposure to risk.

A strong certification brand also inspires confidence among users and healthcare professionals by demonstrating that you are serious about quality and want to ensure your products are assessed to the highest standards.

If you are concerned that your current certification partner is not ready for the regulatory changes, it is time to consider changing your NB now.

## The Notified Body of choice

TÜV SÜD's regulatory, technical and clinical competence is well respected worldwide. We provide ongoing support by ensuring you are the first to know about important regulatory developments. Our industry-leading expertise and world-class reputation can give your company a real competitive edge.

## Three simple steps to transferring your certification

- **Step 1: Transfer application**
  After we collect all relevant information and provide a customised quotation with timelines, you prepare dedicated forms for transfer application.
- **Step 2: Transfer audit**
  Our auditors conduct an on-site audit, which usually lasts 1 to 2 days only. If you have a proven history of compliance, your new certificates will be issued right away.
- **Step 3: Post-transfer activities**
  This includes the EC renewals of your Class III medical devices to get the most out of the 5-year transition period according to the MDD. Class IIa and Class IIb devices will be subject to a dedicated sampling plan based on your current certification.

The timeline for design dossier assessment is 18 months and may include a validity extension up to 5 years.

## Your business benefits

- **Enhance your reputation** – with TÜV SÜD certification marks, which are synonymous with quality and safety the world over.
- **Benefit from a complete testing and assessment solution** – with applied full scope under the EU medical devices' legislation for all types of medical devices.
- **Stay up to date** – with TÜV SÜD's Regulatory Foreign Affairs & Clinical Department, which specialises in market access and the latest worldwide regulations.
- **Save time and cost** – with our comprehensive international accreditations coupled with our extensive global network of offices and laboratories, ensuring you obtain your worldwide product and system certification in a fast, efficient manner.

## Why choose TÜV SÜD?

TÜV SÜD is more than just a certification and Notified Body. We are one of the healthcare sector's most trusted brands. Our comprehensive expertise and sterling reputation has made us the world's leading Notified Body in medical device conformity assessment, with approximately 700 dedicated Medical Health and Services (MHS) experts in major markets around the globe.

## 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 1,000 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:

- Conformity assessment and market approval
- Design dossier assessment
- Medical device testing – CB and NRTL Certification
- Assessments of clinical evaluations
- ISO 13485 – Quality management certification
- ISO 9001 – Quality management system certification
- Medical Device Single Audit Program (MDSAP)

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