



Add value.
Inspire trust.

Orthopedic medical devices

Realising the next generation of safety and reliability.

Industry overview

The orthopedic devices sector is a dynamic field within the medical device industry. Available devices can be categorised, for example, as joint reconstruction, orthobiologics, trauma fixation devices, spinal devices, accessories, braces and arthroscopic devices. The industry is constantly innovating to improve clinical outcomes by adding new products to meet varying needs, with 3D-printed implants and instruments, new biomaterials, computer-assisted surgical procedures and smart implants being just a few examples of the innovative products now available. At the same time, new automation technologies and robotics are increasingly deployed in the manufacturing process, predictably delivering high-quality devices for the growing market. Consequently, the global orthopedics industry is expected to reach an estimated USD 62.6 billion by 2022 and is forecasted to grow at a CAGR of 5.5 per cent from 2017 to 2022¹. An ageing population, rising rates of obesity, orthopedic diseases, degeneration and sports-related injuries are more reasons leading to the increase.

Whether necessitated by age or injury, orthopedic devices offer patients the prospect of shorter hospital stays, faster recovery, restored physical ability and independence. Furthermore, there seems to be a growing preference for minimally invasive surgeries (MIS) and one-time surgeries instead of lifelong dependency on medication.

As new innovations emerge, the research and developmental process can be complex and will be subject to increased regulation and responsibility.

Your challenges

The orthopedic devices industry comprises a few large multinational corporations, many small and medium-sized enterprises (SME), and start-up companies. In a highly competitive environment largely driven by innovation, manufacturers face numerous challenges. Some of the individual concerns of larger firms include innovating faster and consolidating their positions in strategic markets. SMEs, while having the advantage of being fast and nimble may at times be constrained

by their operational processes. For start-ups, technical competencies are typically secondary concerns when compared to their manpower requirements and business strategies. Besides these individual constraints, some of the challenges faced by all manufacturers in the industry are highlighted below.

- **High cost of innovation** – Due to increasing global competition, innovation is crucial for the growth and survival of medical device manufacturers. In connection with that, new ideas and technologies must comply with safety, reliability and performance. Additionally, the design, development and manufacturing of orthopedic devices are complex, time-consuming and cost-intensive processes. Unexpected findings can lead to significant and costly delays.
- **Obligation to conduct pre-market clinical investigations** – With the new MDR in place, the complete product portfolio must be revisited. Manufacturers who intend to continue products that have been earlier placed in the market will need to invest more time and financial resources to establish the required clinical data. As some devices intended for lifelong use are subject to long-term studies, this will likely lengthen the approval process as well. It is important to get in contact with an independent notified body early in the process, reducing the risk of late identification of non-conformities.
- **Stringent requirements of MDR** – The new regulatory changes applicable to orthopedic devices will impose additional requirements relating to CE mark clearance. Some of the key highlights include:
 - Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level
 - Up-classification of all joint replacements and devices in contact with the spinal column
 - EU database on medical devices
 - EU-wide requirement with regards to traceability (implant card, UDI)
 - Reinforcement of the rules on clinical data
- **Compliance to the Medical Device Single Audit Program (MDSAP)** – The MDSAP involves a single regulatory audit of the quality management system that satisfies the needs of the following regulatory jurisdictions: Australia, Brazil, Canada, Japan, USA. The MDSAP will soon become a mandatory requirement for manufacturers who wish to maintain or apply for a medical device licence in specific countries.

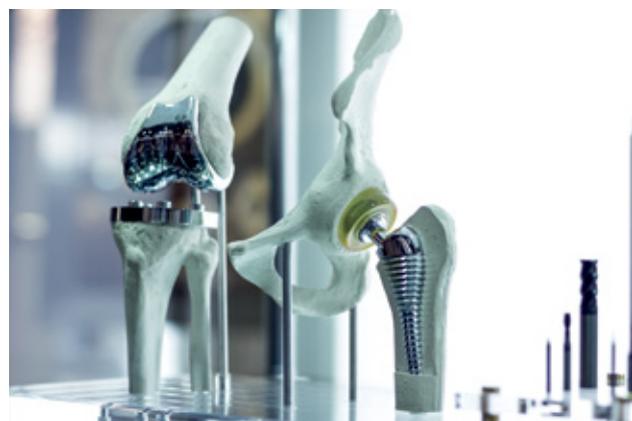
For medical device manufacturers, overcoming these and other challenges requires both in-depth technical knowledge and extensive experience in the processes needed to successfully launch products. These challenges can be especially daunting for small and medium-sized companies, who constitute the majority of medical device manufacturers.

How can we help you?

TÜV SÜD is the world's largest EU Notified Body for all types 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 this field on the vast technical, clinical and regulatory expertise of its staff. Our experts are dedicated to high-risk implantable devices, with expertise ranging from the technical to the clinical aspects and in specific fields covering patient-specific implants, custom-made devices, bioabsorbable materials, robotic surgical procedures and others.

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





TÜV SÜD's services 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 orthopedic devices.
- **Quality system auditing** – Our experts perform 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.
- **MDR trainings and workshops** – We conduct MDR training and workshops covering general MDR requirements and compliance.
- **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 in-house clinical resources cover the various orthopedic specialisations and add value to the devices undergoing the independent scrutiny of

clinical evaluation reports. By having direct access to the clinical reviewers, we are able to offer rapid, high-quality clinical reviews tailored to specific product or customer needs.

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

Your business benefits

- **Access recognised medical device expertise** – by partnering with the largest EU Notified Body in the





world. With a Regulatory Foreign Affairs department 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.

- **Gain predictability** – that is key for the successful development and placement of a medical device on the market. We offer clear timelines that can be tailored to the specific project needs and employ project managers dedicated to guarantee timelines are successfully met.
- **Remain abreast of regulatory changes** – through the active involvement of TÜV SÜD technical professionals in standards development activities related to all types of medical devices and participation 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.
- **Benefit from a single-source solution** – with access to a wide range of review and testing services for high-risk implantable medical devices as required by regulators in major medical markets around the world.

- **Choose an expert partner** – for your business, regardless of whether you are an established global manufacturer, a regional SME or a local start-up.

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 while protecting and promoting the health and safety of patients. Our global network of more than 600 dedicated medical health and services professionals includes 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.

Furthermore, the TÜV SÜD brand and its distinctive blue octagon mark are instantly recognised around the globe as symbols of quality and safety that will increase customer confidence in your brand.

¹<https://www.giiresearch.com/report/luci508826-growth-opportunities-global-orthopedic-device.html>