

QMD Services

Your Notified body for Certification
MDR, IVDR

Because Patient Safety Matters



About QMD Services

QMD Services is the only Notified Body for medical devices and *in vitro* diagnostic medical devices in Austria. QMD has been founded in 2018, focussing on accessibility, transparency and reliable results. We carry out our conformity assessment activities in full compliance with the IVDR and MDR. Our team is committed to ensuring the safety, quality and performance of the medical devices that

our clients bring to the European Union market. We support our clients with lean processes and a high level of responsiveness.

We offer expertise you can trust. We bring together expertise from all over Europe and our partners, combining regulatory competence with local support.



Why choose QMD Services

For many manufacturers, the greatest challenge today is no longer understanding the regulatory requirements. It is finding a Notified Body that is available, responsive and transparent throughout the conformity assessment process.

At QMD Services, this is exactly what we have built our organisation around. We believe that responsiveness is part of quality. Manufacturers should not face unnecessary waiting periods or uncertainty before their conformity assessment even begins. That is why we focus on providing a structured, predictable and transparent certification experience from the very first contact.

When you choose QMD Services, you can expect:

- **An initial meeting typically scheduled within one week** of your enquiry.
- **Immediate preparation of your conformity assessment project** following engagement.
- **A dedicated project manager** who serves as your consistent point of contact throughout the certification process.
- **Clearly defined timelines and transparent communication**, so you always know where your project stands and what comes next.
- **Efficient, standardised assessment processes** designed to minimise unnecessary delays while maintaining the highest level of regulatory rigour.

QUALITY AUSTRIA CENTRAL ASIA

Quality Austria Central Asia (India), established in 2010 as a joint venture between Quality Austria and Peacock Global, extends Vienna's rigorous standards to the Indian market through ISO certifications, inspections, training and specialized services.

This powerful linkage delivers Austrian precision with local expertise, ensuring clients benefit from Vienna's oversight, global accreditations (IQNet, NABCB), and unmatched credibility.

We are the leading company in the TIC Industry. Our main focuses are system and product certification, training and personal certification. We are accredited by Accreditation Austria for system, product as well as personal certification and have many international registrations and accreditations. Further- more, we present the Austrian Excellence Award together with the BMWA (Federal Ministry for Economy and Work) and award the Austria Quality Seal.

With an extensive footprint spanning India and 8 international locations in Asia, QACA delivers globally recognized, cost-effective compliance solutions powered by an unwavering commitment to integrity, technical perfection, and client success.

We adapt our offer according to our clients' needs and support them in achieving their long-term goals!

Medical Device Regulation (EU) 2017/745

The European Medical Device Regulation (MDR) (EU) 2017/745 establishes the legal framework for placing medical devices on the European market. Introduced to enhance patient safety and strengthen surveillance throughout the product lifecycle, MDR applies to a wide range of medical devices, from simple instruments to complex implantable and software-based machines and technologies.

Manufacturers are responsible for demonstrating that their devices meet the applicable General Safety and Performance Requirements, supported by robust technical documentation, risk management, clinical evaluation, and post-market surveillance activities. The regulation places emphasis on clinical evidence, traceability through the Unique Device Identification (UDI) system, and continuous monitoring of device performance once products are on the market.

For most medium- and high-risk devices, an independent Notified Body must assess the manufacturer's quality management system and technical documentation before CE certification can be granted. Certification under MDR provides access to the European market while demonstrating compliance with one of the world's most comprehensive medical device regulatory frameworks.



QMD Services GmbH is an Austrian Notified Body designated under **MDR (Regulation (EU) 2017/745)** for medical devices with the notified body number NB 2962.

QMD's designation covers a wide range of MDR product categories, including:

- Active medical devices
- Non-active medical devices

We have a strong team regarding Software and digital health technologies, including AI applications.

In addition, QMD offers conformity assessment services related to:

- **Article 16 MDR/IVDR** (certain importer and distributor activities)
- **Article 22 MDR** (Systems and Procedure Packs)
- **Article 117 MDR** (medicinal products incorporating a medical device component)

The detailed designated scope is maintained in the European Commission's NANDO database and is subject to ongoing extension activities.



In-vitro Device Regulation (EU) 2017/746

The European In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746 establishes the legal framework for placing in vitro diagnostic medical devices on the European market. The regulation aims to strengthen patient safety, improve the reliability of diagnostic results, and enhance oversight throughout the entire product lifecycle. IVDR applies to a broad range of diagnostic products, including laboratory tests, reagents, calibrators, specimen collection devices, self-tests, companion diagnostics, and software used for diagnostic purposes.

Manufacturers must demonstrate that their devices meet the applicable safety and performance requirements through comprehensive technical documentation, performance evaluation, risk management, and post-market performance follow-up activities. The regulation places increased emphasis on scientific validity, analytical and clinical performance evidence, traceability, and ongoing monitoring of device performance after market placement.

For many IVDs, associated with higher risk, an independent Notified Body must review the manufacturer's quality management system and technical documentation before CE certification can be granted. Compliance with IVDR enables manufacturers to access the European market while demonstrating adherence to a rigorous and internationally recognised regulatory framework for diagnostic devices.



QMD Services GmbH is an Austrian Notified Body designated under IVDR (Regulation (EU) 2017/746) for in vitro diagnostic medical devices with the notified body number **NB 2962**. Since December 2022, QMD has served as Austria's national IVDR Notified Body and today supports manufacturers from Europe and around the world.

QMD's designation covers a broad range of in vitro diagnostic technologies and risk classes, supporting manufacturers of diagnostic products across diverse application areas. The scope includes conformity assessment of both established and innovative diagnostic technologies.

The detailed designated scope is maintained in the European Commission's NANDO database and is continuously expanded in line with market needs and regulatory developments.



Integrated Services

ISO 13485

QMD Services is part of the Quality Austria group and offers manufacturers the benefit of an integrated certification approach.

While QMD performs conformity assessment activities as a Notified Body under MDR and IVDR, Quality Austria provides accredited management system certification services, including **ISO 13485**, the internationally recognised standard for quality management systems in the medical device industry.

By coordinating certification activities where permissible, manufacturers can benefit from aligned audit planning, reduced administrative effort, and efficient communication between certification programs. This helps organisations streamline their regulatory and quality management obligations while maintaining clear separation between accredited certification and independent Notified Body activities.

MDSAP

QMD Services has established a partnership with UL Solutions for the provision of Medical Device Single Audit Program certification.

Through the enhanced MDSAP offering, clients can benefit from increased alignment of audit activities and, where feasible, coordinated certification cycles. This approach supports more efficient use of resources while maintaining the high level of regulatory rigor expected from a Notified Body.

TCP III *(Planned)*

For European manufacturers seeking access to the Taiwanese market, QMD has applied to offer certification services under the **Taiwan Technical Cooperation Program (TCP III)**. This enables manufacturers to leverage internationally recognised conformity assessment activities and benefit from a more efficient pathway towards regulatory acceptance in Taiwan.

Understanding the certification journey

Your Certification Journey with QMD

Bringing a medical device or in vitro diagnostic device to the European market can seem complex, especially for companies navigating regulatory requirements for the first time. At QMD, we understand that certification is not only a regulatory exercise but also a critical business milestone. Our role is to provide a transparent, professional, and efficient conformity assessment process that supports your market access goals while ensuring compliance with MDR and IVDR requirements.

Where do I start?

Many manufacturers ask when they should engage with a Notified Body. The answer is: as early as possible. Through our pre-application process, QMD helps manufacturers understand whether their product falls within our designated scope, identify the applicable classification and conformity assessment pathway, and prepare for the formal application process. Early engagement helps avoid surprises and supports effective project planning.

Am I ready to apply?

A common concern for first-time applicants is whether their documentation and quality management system are sufficiently mature. QMD provides clear application requirements and performs structured completeness checks before the full conformity assessment begins. This enables manufacturers to understand what evidence is required and helps ensure that assessments can proceed as efficiently as possible.

How does the certification process work?

The certification journey typically begins with a pre-application and formal application phase. Manufacturers submit key information such as device classification, intended use, codes, and evidence of an implemented quality management system. This is followed by a completeness review, technical documentation assessment, quality management system audit, clinical or performance evaluation review, and an independent certification decision. Once conformity has been demonstrated, QMD can issue the relevant certificates under MDR or IVDR.

Addressing your individual strengths and needs

Every manufacturer is different. Different technologies. Different risk classes. Different regulatory challenges. Our experienced assessment teams apply the requirements of the EU MDR, IVDR and ISO 13485 with consistency, precision and impartiality, tailoring the conformity assessment process to the specific characteristics of your devices while maintaining full compliance with regulatory expectations.

Our structured and harmonised approach supports robust technical documentation review, transparent decision-making and reliable certification outcomes. By combining regulatory expertise with efficient project management and clear communication, we help manufacturers navigate conformity assessment with confidence.

Choosing QMD Services means partnering with a Notified Body that values not only regulatory excellence, but also responsiveness, predictability and transparency – helping you bring safe, high-quality medical devices and in vitro diagnostics to the European market with confidence.

How long will certification take?

Manufacturers need predictable timelines for product launches and investment planning. QMD has established a structured project management approach and transparent assessment process. Typical timelines depend on factors such as product complexity, documentation quality, responsiveness during deficiency resolution, and regulatory requirements. Our objective is to provide realistic planning assumptions and maintain efficient communication throughout the project lifecycle.

What support can I expect?

At QMD, we believe that transparent communication and responsiveness are key elements of a successful certification journey. Manufacturers benefit from dedicated project management, defined communication channels and clear information regarding the status of their assessment activities. Our goal is to create a professional and predictable certification experience while maintaining the independence and impartiality required of a Notified Body.



Partnering for Long-Term Compliance and Growth

For manufacturers already working with a Notified Body, the challenge is often no longer obtaining the initial certificate. Instead, the focus shifts towards efficiently managing change notifications, adding new products to existing certificates, maintaining compliance, and ensuring that certification activities support business growth. QMD understands these challenges and offers a responsive, technically competent, and predictable certification partnership throughout the entire product lifecycle.

Looking for Additional Capacity?

As the demand for MDR and IVDR certification continues to evolve, manufacturers often seek additional capacity, shorter waiting times, or a certification partner that can support growing product portfolios. QMD's MDR and IVDR designations cover a broad range of device technologies and enable manufacturers to work with a Notified Body focused exclusively on medical devices and in vitro diagnostics.

Managing Changes Efficiently

Successful manufacturers continuously improve products, introduce new technologies, expand indications, and optimise manufacturing processes. Such activities frequently require review and approval by a Notified Body. QMD supports manufacturers through structured change assessment processes, helping ensure that regulatory requirements are addressed while minimising disruption to ongoing business activities.

Transparent Communication and Project Management

Manufacturers value clear communication, predictable processes and timely responses. QMD places particular emphasis on responsiveness, dedicated project management and transparent assessment processes. Our objective is to build long-term relationships based on professionalism, technical excellence and mutual trust while maintaining the independence and impartiality required of a Notified Body.

Supporting Your Global Growth

Many manufacturers have regulatory objectives beyond Europe. Through our cooperation with Quality Austria and international certification networks, QMD can support broader compliance strategies, including ISO 13485 certification, international certification programmes such as MDSAP. This allows manufacturers to benefit from coordinated certification activities across multiple regulatory frameworks.

Expertise for Emerging Technologies

The regulatory expectations for software, digital health technologies and artificial intelligence continue to develop rapidly. QMD has developed strong competencies in software-based medical devices and digital technologies, enabling manufacturers to work with reviewers and experts who understand both technical innovation and regulatory expectations.





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