QMD Services / Costs and Services Overview

QMD Services GmbH is a Notified Body (NB 2962) according to **Regulation (EU) 2017/746 (IVDR)** and also according to **Regulation (EU) 2017/745 (MDR)**. In addition to providing conformity assessment activities for the European medical device market, QMD Services offers services globally. Our team of international experts operates from all over Europe through our head quarter in Vienna, Austria and our operations office in Linz, Austria.

1. Our commitment

At **QMD Services**, our commitment extends beyond conformity assessment. We act as a reliable partner to manufacturers, supporting compliance with the requirements of Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), while contributing to patient safety and public health.

Our **multidisciplinary team**, with expertise in clinical medicine, biomedical engineering, natural sciences, quality management, and regulatory affairs, performs conformity assessments in a consistent, thorough, and impartial manner across a broad range of technologies and risk classes.

We place particular emphasis on **transparency, predictability, and responsiveness throughout the conformity assessment process**. Manufacturers benefit from clearly defined procedures, structured project planning, and continuous communication, supported by a dedicated point of contact.

QMD Services is committed to ensuring the **timely initiation and efficient execution of conformity assessment activities**, while maintaining the highest level of regulatory rigour. Our **harmonised assessment approach** supports robust technical documentation review, well-founded certification decisions, and consistent application of regulatory requirements.

All services are delivered on the basis of clear, individually defined quotations, providing a **high degree of cost predictability** and ensuring that, under agreed project conditions, invoicing remains aligned with the proposed scope and effort.

By combining **technical competence with a structured and service-oriented approach**, we provide a conformity assessment experience that is reliable, transparent, and aligned with regulatory expectations supporting manufacturers in placing safe and compliant medical devices and in vitro diagnostics on the European market.

2. Impartiality and Structured Dialogue

QMD Services is firmly **committed to impartiality** in accordance with Regulation (EU) 2017/745 (MDR), Regulation (EU) 2017/746 (IVDR), and MDCG 2019-6. As a Notified Body, **we do not provide consultancy** or advice on how to achieve compliance. Our role is strictly limited to assessing whether regulatory requirements are fulfilled, ensuring independence, objectivity, and the integrity of all certification decisions.

At the same time, **structured dialogue** is a core element of our service and a key differentiator. It is embedded from the very first interaction and continues throughout the entire conformity assessment lifecycle, from initial contact to certification and beyond.

We offer an **initial meeting free of charge**, providing manufacturers with early orientation and clarity on the conformity assessment process. From this point forward, clients benefit from **continuous, direct, and structured communication with our experts**. Our approach ensures that you are consistently informed, supported, and able to anticipate the next steps in your certification project.

All communication is conducted in line with regulatory constraints: we clearly define what needs to be fulfilled, without advising on how to fulfil it. This enables efficient and transparent interactions while preserving the manufacturer's full responsibility for demonstrating compliance.

By combining strict impartiality with proactive, structured, and continuous dialogue, QMD Services delivers conformity assessment that is both compliant and highly accessible, ensuring that you are supported at every stage without compromising regulatory independence.

3. Process Timelines

The **time from initial contact to certification** depends on the readiness of the manufacturer, the complexity of the device, and the quality of the submitted documentation. At QMD Services, we do everything on our side to keep the process efficient, avoid unnecessary delays, and maintain continuous communication so that open questions and nonconformities can be resolved as quickly as possible. In line with the applicable regulatory requirements and the timelines placed upon us as a Notified Body, we plan and conduct our activities accordingly.

Preparation is key. Where the technical file and quality management system documentation are well prepared, the conformity assessment process can progress more efficiently and usually requires fewer review rounds. Where documentation is incomplete, unclear, or requires substantial correction, the process will naturally take longer. Current survey data also show that incomplete submissions remain a major driver of delay and that the **time from application to certificate varies significantly** depending on the readiness of the manufacturer and the Notified Body processes.

From a process perspective, we aim to move quickly from pre-application to a complete application, followed by structured project planning and timely start of the conformity assessment activities. In practice, this means that the **manufacturer and QMD Services work in close cooperation throughout the process**. We keep the dialogue direct and pragmatic, and we expect the same level of responsiveness from our clients in order to keep the project on track. This cooperative approach is essential for meeting the **agreed timelines** and supporting market access in a predictable way.

Where external consultation is required, or where the file requires additional review rounds or corrective actions, the overall timeline will extend accordingly. Under specific circumstances, **expedited procedures** may also be available, depending on the regulatory context and the applicable project conditions.

4. Reviewer Expertise and Available Resources

QMD Services ensures that all conformity assessment activities are performed by **suitably qualified personnel with the necessary expertise**, in accordance with Regulation (EU) 2017/745 (MDR), Regulation (EU) 2017/746 (IVDR), and the requirements for Notified Bodies under Annex VII.

Our technical competence is defined by the **scope of designation**, which is publicly available in NANDO. We only accept applications that fall within this scope and for which we can ensure appropriate expertise and resources.

A key element of our service model is the **immediate availability of resources** for the application and onboarding phase. We maintain sufficient capacity to initiate the application process without delay, allowing manufacturers to receive timely feedback on feasibility and next steps.

Project planning and resource allocation are agreed within a structured, bilateral acceptance process, aligned with current regulatory expectations, including the principles set

out in the Implementing Act related to Annex VII. This ensures that timelines, responsibilities, and documentation readiness are clearly defined from the outset.

Conformity assessment activities and timelines are scheduled based on the agreed readiness of technical documentation. Adherence to these timelines enables efficient project execution and supports **reliable market access planning**. For keeping agreed timelines it is mandatory the clients upload their technical documentation as agreed in the onboarding process.

By combining defined technical expertise, proactive resource planning, and structured onboarding, QMD Services provides a predictable and timely pathway into conformity assessment.

5. Billing and Invoicing

QMD Services applies a **transparent and structured approach to billing**, reflecting the individual nature of conformity assessment activities. As services are highly dependent on device type, classification, and technical complexity, detailed and binding quotations can only be issued once sufficient information has been collected during the onboarding process. Prior to this stage, indicative cost estimates may be provided; however, these remain subject to adjustment as further details become available. Our costs are transparent and published on the QMD Services website.

5.1. Onboarding Phase

The onboarding phase consists of two defined steps, each associated with a dedicated fee:

- **Pre-Application Fee:** A fixed, one-time fee for new clients, initiating the onboarding process and structured dialogue. This phase includes initial regulatory orientation, client profiling, the preparation of a tailored quotation for conformity assessment services and the establishment of the application framework.
- **Application Fee:** A variable fee, charged per application, depending on the number and complexity of devices. This phase covers detailed application review, scope verification against designation, preliminary assessment of documentation,.

Both fees constitute a commitment to the respective process phase and enable QMD Services to allocate the necessary expertise and resources. Clients have the right to withdraw their application at any time without penalty in the onboarding phase.

5.2. Conformity Assessment Phase

Following successful completion of the application phase, conformity assessment activities are performed based on an individually agreed contract and quotation.

Billing is structured per defined project milestones rather than on a time-based or periodic basis. Each invoice reflects the agreed scope and effort associated with the respective milestone, ensuring alignment between delivered services and invoicing.

In specific cases, partial advance payments may be required prior to the initiation of certain conformity assessment activities. Any such arrangements are clearly defined in the individual quotation.

By combining transparent onboarding, specifically tailored quotations, and milestone-based invoicing, QMD Services ensures a **high degree of cost clarity, predictability**, and alignment with the actual scope of work. Figure 1 below shows a graphical summary of the process:

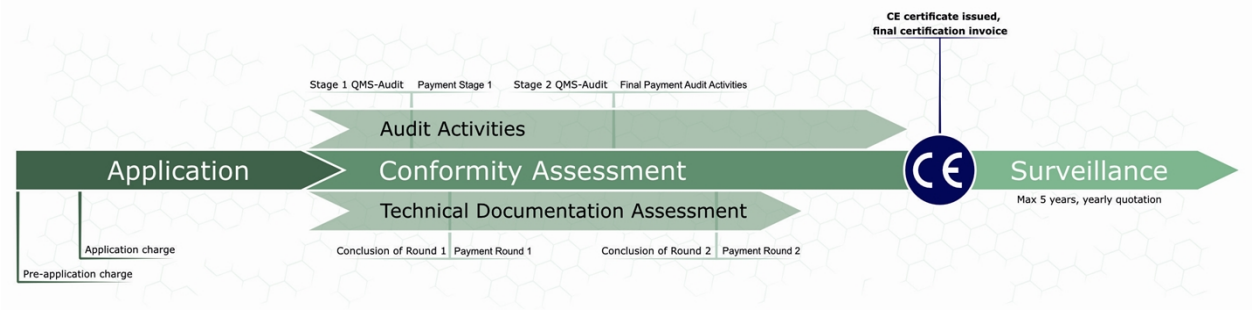

Figure 1. Service Billing Interval. Invoices are issued on new application initiation at the end of process stages, or on a monthly basis for longer running activities.

6. Expected costs by device class

The average estimated initial certification costs by device class, assuming a complete, well-structured technical file and a single assessment round, are summarized below (see Figures 2 and 3).

The shown cost estimates include the costs for pre-application, application, TD assessment, final review, certificate costs and annual certificate fee. It assumes a single device not including any special features such as software, animal tissues, near patient tests, etc. For these specific features we align with the Team-NB Code of Conduct where a guidance for the duration of each conformity assessment task is given. This cost estimate does not include, third party consulations, or additional rounds of technical documentation assessments and follow-up audits in case of questions or non-conformities. In case of additional rounds are required, we will prepare a quotation for each round.

Audit activities cannot be included in the estimates shown, as they vary greatly depending on the number of employees, locations and specifics of the client organisation. IAF Mandatory document 9 is a guidance for audit duration applied by QMD Services.

Applying for additional devices will not scale certification cost linearly due to consolidation of on-site audits costs, and the option for sampling for devices with the same intended purpose (e.g. EMDN code) in some risk classes. A detailed individual quotation will be generated as part of the pre-application services to reflect the clients specific product portfolio and organisation.

The actual cost will highly depend on the quality of the technical documentation you provide and the preparation of your quality management system. Where we raise questions or non-conformities, additional rounds of conformity assessment will need to be scheduled. These follow-up activities will focus on the requirements in question and will therefore be less time consuming and costly per outcome than the initial assessment / audit. Always have in mind that only 3 rounds of questions/non-conformities are allowed.

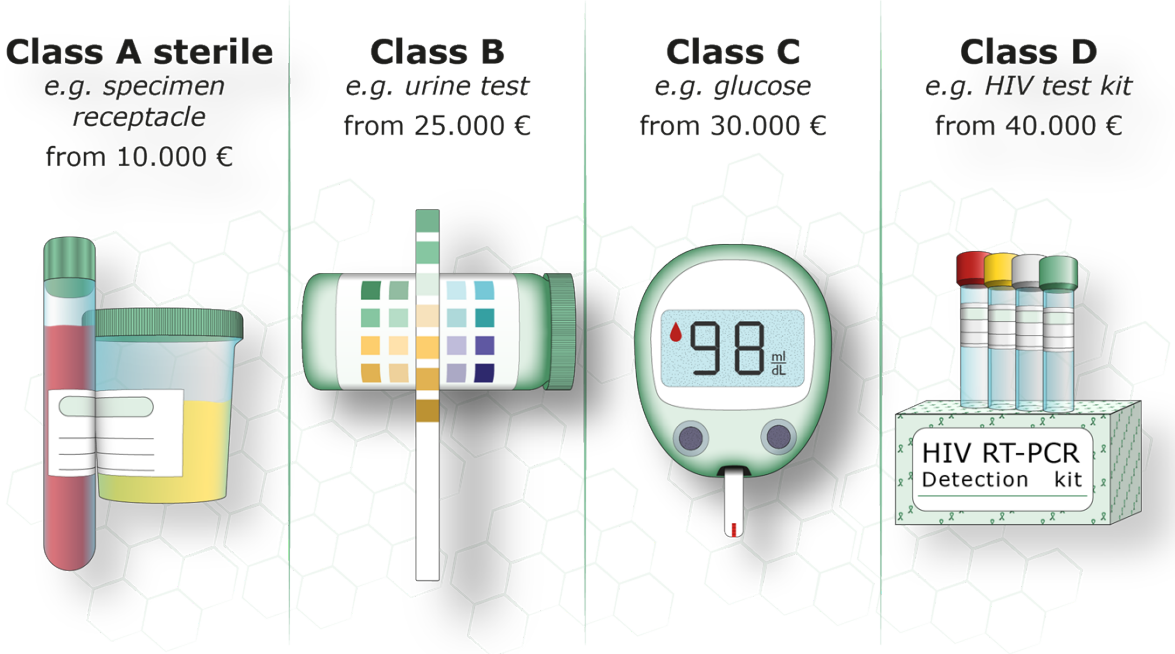

Figure 2. Average estimated cost by device class for initial certification (IVDR)

Figure 3. Average estimated cost by device class for initial certification (MDR)

Invoices are issued for each completed task after the contract has been signed. Annual fees are invoices for permissions to use certificates and associated logos and issued in advance for each year. After certification, we will issue quotation summarising the effort for maintainance of certificate and post market surveillance on a yearly basis. Additional costs (e.g. unannounced audits, vigilance costs) will be invoiced as they arise based on our current price list as available on our website.

7. Working Together

The conformity assessment process is most efficient when both parties work in a coordinated and timely manner according to an agreed timeplan. QMD Services is committed to clear communication, structured review, and timely feedback. Manufacturers, in turn, play a decisive role by submitting complete documentation to the agreed dates, responding promptly to questions, and maintaining an effective QMS.

A well-prepared manufacturer and a responsive Notified Body create the best conditions for a smooth process and a successful certification outcome.

We look forward to
working with you!

Call or email us today for further details

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Changes Made to the document:

Complete change history:

Ver. 1 | Effective Date 2024-12-01: Change: // Transfer of Initial Version to eQMS // Major changes:

Process description

Details on billing and invoicing process

Correction of process descriptions

Adaption of process graphics (Figure 1)

Correction of price graphics

- Ver. 2 | Effective Date 2025-05-26: Change:
- Added information on conditions regarding upfront payments of Pre-Application and Application Fees. Adaption to Price Overview changes. - Correction of IVDR and MDR related graphics; adding Class A to figure 2; change of images for IVD and MD examples - Added information on changes during surveillance - Restructuring of text elements for better readability. - Corrected "IBzAN" to "IBAN"
- Providing access to external personnel. Added "QMD Contractors" site - Minor error corrections.

- Ver. 3 | Effective Date 2026-07-30: Change: Restructuring text for better readability and to remove duplicated text sections; adaption to milestone based billing; Change of process graphic in accordance with chages above
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Signatures:

Controlled Document Approved:	I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.
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