1. PRICE POLICY

TRANSPARENT We are committed to full pricing transparency. All fees and charges are clearly communicated in advance, with no hidden costs. Our clients receive detailed quotations and information on billing. Invoices are aligned with quotations. Services are thus clearly traceable and comparable.

TRUSTED We build long-term relationships with our clients based on integrity and mutual trust. Our pricing structure reflects our commitment to fairness and value, ensuring that clients can rely on us as a consistent and dependable partner in MDR and IVDR conformity assessment activities.

EQUAL RIGHTS We ensure that our pricing and service conditions are applied consistently. Discounts for services are provided only on the basis of the specified QMD Services grants. This complies with the requirement of coherent, fair and reasonable terms and conditions of the Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

PERFORMANCE ORIENTED QMD Services does not make any framework contracts without linkage to a specific certification project. There are therefore no commercial expenditures (penalties, contract cancellation fees, compensation payments, etc.), upon termination of the contract. You only pay for the services you receive.

LEGALLY COMPLIANT A certificate will only be issued if the product or system under assessment meets all applicable relevant requirements, or other relevant certification criteria.

2. Price Overview

Applicable for all services starting from 2025-11-01

Type of Service	Type of Fee	Fees	Factors influencing the calculation of fee charged	Fee range (min-max)
1 Administrative charges				
1.1 Pre-application				
Pre-application charge	flat fee	€ 933.-	Includes the initiation of classification review and code assignment. Setting up sampling plan basis, resource planning, and one individual quotation. Non-refundable.	N/A
1.2 Application				
Application charge	minimum fee	Min. € 2177.-; the application fee will be adapted depending on number of devices and their complexity	Includes the initiation of planning of conformity assessment, resource planning, QMS Application completeness check. Non-refundable.	N/A
1.3 Additional costs				
Travel and accommodation expenses	at cost	Travel by car is charged per km: official mileage allowance as per definition by Austrian law; other travel expenses (e.g. flight, taxi, accommodation expenses) are charged at cost.		N/A
Travel time	hourly	per travel hour: € 133.-		N/A
Administrative costs (e.g. handling of external services like laboratories, consultation, Eudamed)	hourly	€ 311.-		N/A
2 Conformity Assessment The necessary conformity assessment activities and their scope are determined individually for each order. The services are charged according to expenditure of time with the following fees				
2.1 Assessment				

Type of Service	Type of Fee	Fees	Factors influencing the calculation of fee charged	Fee range (min-max)
Technical documentation assessment Assessment of changes and vigilance data	hourly	€ 377.-	Time for technical documentation assessment is strongly influenced by completeness, clarity, and quality of the technical documentation submitted	N/A
Clinical Experts and other external experts Clinical/Performance Evaluation Assessment (CEA/PEA) Evaluation/review of the Periodic Safety Update Report (PSUR) Validation of the Summary of Safety and Performance (SSP) Validation of the Summary of Safety and Clinical Performance (SSCP)	hourly	min. € 407.-	Costs depend on cost incurred by external specialists	€ 407.- to € 716.-
Consultation mechanism: ▪ Expert panel consultation; ▪ Consultation of a medicinal product authority for a companion diagnostic; ▪ Consultation of an EU reference laboratory for performance verification and batch release; ▪ Consultation with the coordinating competent authority for devices utilizing animal tissues.	flat fee	calculation of incurred costs by authorities, reference laboratories, EMA, etc. + 10% review charge	Depending on external costs	N/A
2.2 Auditing				
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier, Reporting) Unannounced Audits Certification activities Article 16(4)	hourly	€ 311.-	Audit time based on IAF MD9 as applicable plus min. 25% specific MDR/IVDR time; for multi-site audits IAF MD1 will be applied	N/A
2.3 Product testing				

Type of Service	Type of Fee	Fees	Factors influencing the calculation of fee charged	Fee range (min-max)
Product / Laboratory testing	processing fee	20% of incurred laboratory cost (laboratory costs to be covered in addition by manufacturer)		N/A
Batch release setup (Effort for batch release setup incl. lab contract)	hourly	€ 377.-	Number of products	N/A
Batch release (Laboratory testing and review of manufacturer's batch documentation)	flat fee, per batch	€ 480.-		N/A
Disposal of test samples	processing fee	calculation of incurred costs		N/A
3 Other costs				
Issuing of certificates on paper, additional certificates, changes on certificates	price per unit	€ 172.-		N/A
Annual certificate fee IVDR/MDR (right of use including first issue and publication of the certificate, certificate in English language pdf format)	flat fees, per certificate	SMEs*: € 750.-; large manufacturers: € 1.500.-		€ 750.- or -€ 1.500.-
Annual certificate fee ISO 13485 by Quality Austria	flat fees, per client	SMEs*: € 430.-; large manufacturers: € 850.-		€ 430.- or -€ 850.-
Notarial certifications and apostilles	processing fee	incurred costs plus handling fee of 20% of incurred cost		N/A
Procedure for withdrawal, restriction, suspension of a certificate	hourly	€ 311.-	already paid fees are not refundable, not yet paid but rendered services must be fully paid	N/A
Procedure at discontinuation of conformity assessment or certification activities Article 16(4)	hourly	€ 311.-	already paid fees are not refundable, not yet paid but rendered services must be fully paid	N/A

Notes:

- All fees are exclusive of VAT
- Review and approval of certificate changes will be dependent on the submission of satisfactory documentation and timely responses to questions raised by QMD Services.

- The fees quoted are for illustration purposes only at current rates and are subject to annual review and adjustment.
- Regional discounts may apply.

3. Explanation for "Price Overview" items

Fees are charged as either

- "minimum fee" which is a base cost for the provision of a service over the application process. Additional fees apply depending on the number of devices and their complexity within one application.
- "flat fees", i.e. fixed fees that do not depend on the time and resources needed.
- "hourly", i.e. fee items based on the time allocated for the activity per specific role.
- processing fees, i.e. handling cost of externally provided services.

In addition to such fees, duly justified external costs are claimed as expenditure (e.g. travel expenses, costs for external testing).

In case fees depend on factors other than time (e.g. travel expenses, external laboratory costs), those are clearly stated.

4. Classification in small and medium organizations

Reduced annual certificate maintenance fees are offered to address the interests of small and medium-sized enterprises. The SME definition of QMD Services is based on one single criteria:

- number of employees: less than 50 permanent employees