
1. PRICE POLICY

TRANSPARENT The hourly costs per service are listed in the quotation and in the invoice. Services are thus clearly traceable and comparable.

TRUSTED QMD Services guarantees quality. On-site services with which the customer is not satisfied will not be charged based on the terms and conditions for services provided by QMD Services.

EQUAL RIGHTS The current prices are always applicable. 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 commercially binding multi-year contracts. There are therefore no commercial expenditures (penalties, contract cancellation fees, compensation payments, etc.), upon termination of the contract.

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

2. Price Overview

Applicable for all services starting from 2024-04-01

Type of Service	Type of Fee	Fees	Factors influencing the calculation of fee charged	Fee range (min-max) ¹
1 Administrative charges				
1.1 Pre-application				
Pre-application charge	minimum charge	€ 873.-	Includes the initiation of classification review and code assignment. Setting up sampling plan and audit program, resource planning, one quotation. Non-refundable.	N/A
1.2 Application				
Application charge	minimum charge	€ 2037.-	Includes the initiation of planning of conformity assessment, resource planning, QMS and TD review. Non-refundable.	N/A
1.3 Additional costs				
Travel and accommodation expenses	at cost	per km: official mileage allowance accommodation expenses charged at cost.		N/A
Travel time	hourly	per travel hour: € 129,-		N/A
Administrative costs (e.g. handling of external services like laboratories, consultation, Eudamed)	hourly	€ 291.-		N/A

¹ More information on necessary conformity assessment time can be found on our web page at <https://www.qmdservices.com/ce-marking-prices-ivdr/>

Type of Service	Type of Fee	Fees	Factors influencing the calculation of fee charged	Fee range (min-max) ¹
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				
Technical documentation assessment Assessment of changes and vigilance data	hourly	€ 352.-	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. € 377,-	Costs depend on cost incurred by external specialists	€ 377,- to € 620,-
Consultation mechanism: <ul style="list-style-type: none"> ▪ 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

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Type of Service	Type of Fee	Fees	Factors influencing the calculation of fee charged	Fee range (min-max) ¹
2.2 Auditing				
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier, Reporting) Unannounced Audits Certification activities Article 16(4)	hourly	€ 291,-	Audit time based on IAF MD9 as applicable; for multi-site audits IAF MD1 will be applied	N/A
2.3 Product testing				
Product / Laboratory testing	processing fee	20% of incurred laboratory cost (laboratory costs to be covered in addition by manufacturer)		N/A
Batch release (Laboratory testing and review of manufacturer's batch documentation)	hourly	€ 352,-		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	€ 163,-		N/A
Annual certificate fee IVDR (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 expiry, withdrawal, revocation, restriction, suspension of a certificate	hourly	€ 291.-	already paid fees are not refundable, not yet paid, but rendered services must be fully paid	N/A

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Type of Service	Type of Fee	Fees	Factors influencing the calculation of fee charged	Fee range (min-max) ¹
Procedure at discontinuation of conformity assessment or certification activities Article 16(4)	hourly	€ 291.-	already paid fees are not refundable, not yet paid, but rendered services must be fully paid	N/A

Notes:

- All fees are exclusive VAT
- Review and approval of certificate changes will be dependent on the submission of satisfactory documentation and timely responses to questions raised by QMD.
- The fees quoted are for illustration purposes only at current rates and are subject to annual review and adjustment.
- Invoices will be carried out at rates prevailing at the time of the audits/assessments.

3. Explanation for "Price Overview" items

Fees are charged as

- "minimum charge" is a base cost for the provision of a service over the pre- and application process. Any additional charges will be billed separately.
- "flat fees", i.e. fixed fees that do not depend on the time and resources needed (based on actual costs incurred).
- "hourly", i.e. fee items based on the time allocated for the activity.
- 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 (example the complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, number nonconformities raised, and rounds of reviews needed), those are clearly stated.

4. Classification in small and medium organizations

The interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC are considered by offering differing annual certificate maintenance fees.

The SME definition is based on the definition of the European Commission (see [EU recommendation 2003/361](#)), which is based on three criteria:

- number of employees
- annual sales
- annual balance sheet

The category of micro, small and medium-sized enterprises include enterprises employing fewer than 250 persons and having an annual turnover of up to EUR 50 million, or whose annual balance sheet does not exceed EUR 43 million.