
1.1 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.

1.2 Price Overview

Type of Service	Type of Fee	Fees	Factors influencing the calculation of fee charged	Fee range (min-max) ¹
1 Administrative charges				
1.1 Contract Advance Payment (non-refundable down payment for Services)				
Application fee	Contract Advance Payment non-refundable down payment for Services	20% of committed order volume	Depending on contract sum	
Administrative fee related to changes	Contract Advance Payment non-refundable down payment for Services such as scope extensions and re-certification	20% of committed order volume	Depending on contract sum	
Annual certificate maintenance fee (right of use including first issue and publication of the certificate, certificate in English language pdf format)	flat fees	SMEs*: € 750,-; large manufacturers: € 1.500,-		€ 750,- - € 1.500,-
1.2 Additional costs				
Travel and accommodation expenses	at cost	per km: official mileage allowance accommodation expenses charged at cost.		
Travel time	hourly	per travel hour: € 125,-		
1.3 Other costs				
Issuing of certificates on paper, additional Certificates, changes on certificates	price per unit	€ 150,-		
Notarial certifications and apostilles	processing fee	calculation of incurred costs		

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
Procedure for expiry, withdrawal, revocation, restriction, suspension of a certificate		already paid fees are not refundable, not yet paid, but rendered services must be fully paid		
Procedure at discontinuation of conformity assessment or certification activities Article 16(4)		already paid fees are not refundable, not yet paid, but rendered services must be fully paid		
All fees are exclusive VAT				
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 Auditing				
Planning of conformity assessment or certification procedure and completeness check Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier) Unannounced Audits Certification activities Article 16(4) Reporting and EUDAMED Upload	hourly	€ 275,-	Audit time based on IAF MD9 as applicable; for multi-site audits IAF MD1 will be applied	e.g. for organization with 1-5 employees 24 hours of audit for initial certification is adequate (for more information, see IAF MD9)
2.2 Documentation Review / Consultation				
Technical documentation assessment 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) Assessment of changes	hourly	€ 330,-	Time for technical documentation assessment is strongly influenced by completeness, clarity, and quality of the technical documentation submitted	QMD Services accepts only three rounds of questions regarding the technical documentation within the review process

Information contained in this document is **CONFIDENTIAL – PRIVILEGED** and only for the information of the intended recipient and may not be used, published or redistributed without the prior written consent of QMD Services GmbH

Type of Service	Type of Fee	Fees	Factors influencing the calculation of fee charged	Fee range (min-max) ¹
Clinical Experts and other external experts Clinical/Performance Evaluation Assessment Report (CEAR/PEAR)	hourly	min. € 350,-	Costs depend on cost incurred by external specialists	€ 350,- - € 600,-
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; ▪ Consultation of an EU reference laboratory for batch testing; ▪ Consultation with the coordinating competent authority for devices utilizing animal tissues. 	Flat fee	calculation of incurred costs by authorities, reference laboratories, EMA, etc. + 10% handling and evaluation charge	Depending on external costs	
2.3 Product testing				
Product testing in accredited laboratory / testing in EU reference laboratory (including preparation and reporting but excluding expenditures incurred for external tests)	Flat fee	20% of incurred laboratory cost (laboratory costs to be covered in addition by manufacturer)		
Batch testing verification	hourly	€ 330,-		
Disposal of test samples	processing fee	calculation of incurred costs		

Notes:

- Review and approval of certificate changes will be dependent on the submission of largely 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.

*Information contained in this document is **CONFIDENTIAL – PRIVILEGED** and only for the information of the intended recipient and may not be used, published or redistributed without the prior written consent of QMD Services GmbH*

1.3 Explanation for "Price Overview" items

Fees are charged as

- "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.

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.

1.4 CLASSIFICATION IN SMALL AND MEDIUM ORGANIZATIONS

The interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC are taken into account by 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.