

**Assessment Services and Prices
of DQS Medizinprodukte GmbH
valid from January 01, 2025**



System assessment - QM certification	
The duration of the system audits is determined based on the company information provided in the basic data. One audit day (person day; PT) is 8 hours.	
Normative system assessment	
ISO 9001	1.450 € / PT
ISO 15378	1.450 € / PT
Normative system assessment medical device	1.640 € / PT
(DIN EN) ISO 13485	
Regulatory system assessment	2.560 € / PT
MDSAP, MDR (EU) 2017/745, MDD 93/42/EEC (MDR Artikel 120), TCP III	
Combined system assessment	2.700 € / PT
combined assessment of several certification programs.	
Unannounced audits	5.400 €
according to MDR (EU) 2017/745 as well as according to MDD 93/42/EEC (MDR Article 120). Price incl. pre- and post-processing of the audit when using 2 auditors with audit duration of 1 PT. Additional services to be provided will be charged with 320 € / hour.	
Other system assessments	according to effort
e.g. change notifications, follow-up assessments, event-related system assessments. Services to be rendered are charged at 320 € / hour.	

Evaluation Technical Documentation (TD) - Product Certification	
The duration of TD assessments is determined based on the risk class of the products being assessed. A review day (person day; PT) is 8 hours.	
Evaluation Technical Documentation	2.560€ / PT
according to MDR (EU) 2017/745 as well as according to MDD 93/42/EEC (MDR Article 120)	
Evaluation safety report (PSUR)	according to effort
Services to be provided are charged at 320 € / hour.	
Evaluation safety report and clinical performance (SSCP)	according to effort
Services to be provided are charged at 320 € / hour.	
Involvement of external clinical experts	4.000 €
Price incl. reporting with test duration of 1 PT. Additional services to be provided will be charged with 320 € / hour.	
Involvement consultation procedure	according to effort
Services to be provided are charged at 320 € / hour.	
Other assessments	according to effort
e.g. change notifications, re-evaluations, event-related evaluations of the technical documentation. Services to be provided are charged at 320 € / hour.	

QM- and product certification - result reports	
Normative system assessment	
ISO 9001	1.495 €
The result report for the advancement assessments (surveillance audit) is charged with 750 €.	
ISO 15378	1.495 €
The result report for the advancement assessments (surveillance audit) is charged with 750 €.	
Normative system assessment medical device	1.700 €
(DIN EN) ISO 13485	
Regulatory system assessment	2.560 €
MDSAP, MDR (EU) 2017/745, MDD 93/42/EEC (MDR Artikel 120), TCP III	
Combined system assessment	2.700 €
combined assessment of several certification programs	
Unannounced audits	1.300 €
according to MDR (EU) 2017/745) as well as according to MDD 93/42/EEC (MDR Article 120).	
Evaluation Technical Documentation	according to effort
according to MDR (EU) 2017/745) as well as according to MDD 93/42/EEC (MDR Article 120). Services to be provided are charged at 320 € / hour.	
Other system assessments / or evaluations of the TD	according to effort
e.g. change notifications, follow-up assessments, event-related system assessments. Services to be rendered are charged at 320 € / hour.	
Extract or complementary report	according to effort
Extract or complementary reports on the above results reports. Services to be provided are charged at 320 € / hour.	

Other assessment, testing and service activities

Service fee

included

Each certified company is charged an annual fee that covers basic service activities. It includes services such as certification planning, implementation and follow-up activities, as well as certificate issuance and administration. In addition, it includes a flat fee for required project meetings, maintenance of external databases, and specified market surveillance activities. The amount of the fee depends on the employees and locations covered by the certificates.

Total number of employees	Service basic amount		Flat rate annual service hours
	Normative certification	Regulatory certification	
1 – 45	450 €	1.700 €	4 Hours
46 – 625	1.200 €	2.700 €	8 Hours
> 625	2.200 €	5.200 €	16 Hours

Service fee - additional effort

according to effort

Should additional service hours be required (e.g. due to change notifications, processing of incident reports, communication with authorities), these will be charged at 320 € / hour.

Service fee - certification committee

according to effort

For all test reports submitted to the certification committee for certification, a test fee of 10% of the previous total test fees will be charged (but max. € 3,000)

Physical product testing

according to effort

e.g. biocompatibility testing, electrical safety and performance testing, EMC (electromagnetic safety) testing. Physical product testing is performed by subcontractors.

Completeness- and feasibility check

320 € / hour

First review free of charge, any further review due to incomplete or incorrectly submitted documents.

Audit preparation time

0,5 PD per Standard

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Complementary additional services	
Planning meeting on site at the customer	320 €
The costs are per DQS MED participant and per hour or part thereof. Please note additional travel expenses.	
Planning meeting in the DQS MED facilities	160 €
The costs are per DQS MED participant and per hour or part thereof.	
Membership MED Xpert Lab (mostly in German language)	
For DQS customers:	350 €
Standard fee:	890 €
Annual subscription to a webinar expert series on regulatory topics with at least 10 dates per year.	
Translations of assessment and test reports	according to effort
Up to 10 pages 600 €, beyond that each additional page 25 €.	
Special procedures	according to effort

Certificates and attestations	
<p>The issuance of a certificate or attestation requires the positive completion of the underlying assessment.</p> <p>For more information on the use of certificate symbols, please refer to our certificate symbol usage policy in the web downloads at www.dqsglobal.com.</p>	
<p>Certification fees Use and publication of certificates and attestations during their validity (per certificate/attestation).</p>	
ISO 9001	480 € / Year
ISO 13485, ISO 15378	1.000 € / Year
TCP III (incl. Taiwan Cover Letter)	1.500 € / Year
MDSAP	1.050 € / Year
MDD 93/42/EEC	1.050 € / Year
MDR (EU) 2017/745	1.050 € / Year
Issuance of excerpt certificates as well as changes	125 € / Page
Issuance of additional language variants (GER, EN)	125 € / Page
Please note that in the event of changes to the underlying certificates and attestations, issued language variants must also be reissued.	
List of other language variants	according to effort
Please note that in the event of changes to the underlying certificates and attestations, issued language variants must also be reissued.	
Notarization of a certification	300 €
Certificate apostille	300 €
Adaptation Confirmation Letter according to Regulation EU 2023/607	1.030 €
Content confirmation or supplementary letters	260 €
Your company logo on your certificate	105 € / Logo
Personal certificate handover by DQS representative	acc. to effort
Please note additional travel expenses.	
Printing and sending certificates and attestations	20 €
Reprinting of certificates or attestations	20 €
Publication on DQS Homepage	included
Cancellation and termination of pending assessments	acc. to effort
Cancellation and termination of regulations of existing certificates and regulations	390 €

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Database entries, registrations (DMIDS, EUDAMED, MDSAP REP-s, etc.)	
Initial registration (initial or re-certification)	320 € / hour
In the course of a notifiable change, each	130 €
Customer initiated notifications	acc. to effort

Incidental costs	
Travel times	125 € / hour
Charge per hour or part thereof from simple travel times over 2 hours (from residence). Maximum charge for domestic travel (border union) 8 hours, for intercontinental travel max. 24 hours, per one-way trip.	
Mileage allowance	0,69 € / km
Travel times	according to effort
Train: 1st class Flight: Economy Class (Intercontinental: Premium Economy or Business Class according to travel policy for external auditors)	
Costs in each case plus incurred costs for public transport, cab or rental car.	
Accommodation	according to effort
We ask that you provide or reserve a reasonable, nearby place for the auditor(s) to stay overnight.	
Expenses	not charged

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About this price list

Valid from 01.01.2025. All previous price lists lose their validity with the publication of this price list. The above fees are net prices and do not include the statutory value-added tax.

The General Terms and Conditions of DQS Medizinprodukte GmbH apply in the current version.

Use of the DQS certificate symbol

With a certificate from DQS Medizinprodukte GmbH, you demonstrate to your entire social environment your will to deliver on performance promises. As a proof of confidence of our customers, as a sign of their loyalty and satisfaction with the quality of our services, we are pleased about the use of the worldwide protected DQS certificate symbol: for example, on business stationery or brochures, on the Internet, at trade fairs, vehicles or in advertising. The certificate symbol is directly related to the certified organization and its management system.

For more information on the use of certificate symbols, please refer to our certificate symbol usage policy in the web downloads at www.dqsglobal.com.

Effort calculation

Please ask for an individual offer:

The assessment of a company is planned individually. Decisive factors include the variety of products (goods and services), complexity of work processes/procedures, special product features, environmentally relevant equipment, requirements from legal regulations, company size, number of employees, degree of automation, organizational structures and location distribution. The respective valid accreditation and approval regulations are applied. After determination of the effort, the assessment days are agreed with the customer in writing.

Audit days comprise 8 hours per day. Assessments or follow-up assessments are carried out on site and/or by document review, depending on the procedural step.

Project planning

Assessments for several locations, for groups of companies and corporate groups are planned on request in an annual project meeting on site with the customer. The appointed audit manager incorporates changes and wishes of the customer as well as previous audit results into the planning. If required, other auditors can also take part in the project meeting.