

Assessment services and prices

DQS Medizinprodukte GmbH

Valid from: 01.01.2026



Auditing and certification services

Auditing		
▪ MDR (Number of FTEs; number of sites; factors for audit increases/reductions; planning and reporting)	Per day	2,760.-
▪ MDSAP (Number of FTEs; number of sites; Number of countries, factors for audit increases/reductions; planning and reporting)	Per day	2,760.-
▪ TCP III (Number of FTEs; number of sites; factors for audit increases/reductions; planning and reporting)	Per day	2,760.-
▪ ISO 13485 (Number of FTEs; number of sites; factors for audit increases/reductions; planning and reporting)	Per day	1,770.-
▪ ISO 15378 (Number of FTEs; number of sites; factors for audit increases/reductions; planning and reporting)	Per day	1,560.-
▪ ISO 9001 (Number of FTEs; number of sites; factors for audit increases/reductions; planning and reporting)	Per day	1,500.-
▪ Combined system assessment (combined assessment of several certification programs)	Per day	2,920.-
▪ Unannounced Audit (ording 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 PD. Additional services to be provided will be charged at 345€ / hour)		5,520.-
▪ Other system assessments (e.g. change notifications, follow-up assessments, event-related system assessments. Services to be rendered are charged at 345€ / hour.)	Per hour	345.-
▪ Audit preparation time	0,5 PD per standard	
▪ Application Management Fee (Maturity of QMS; Completeness and Quality of submission)		2,760.-

Technical Documentation Review + Results Reports		
▪ Technical Documentation Review & Evaluation Technical Documentation (Device complexity; completeness and quality of the submitted file)	Hourly	345.-
▪ Clinical Assessment (CEAR) (Device complexity; completeness and quality of the submitted file)	Hourly	460.-
▪ Expert Panel Consultation		Effort based
▪ Changes of the QM System (Complexity of the QM change, completeness and quality of the submitted file)	Hourly	345.-
▪ Evaluation/review of the Periodic Safety Update Report - PSUR (total effort required: 2 PD)	Daily	2,760.-
▪ Evaluation safety report and clinical performance - SSCP (total effort required: 2 PD)	Daily	2,760.-
▪ MDR (EU) 2017/745 Report	Flat fee	2,760.-
▪ MDSAP Report	Flat fee	2,760.-
▪ ISO 9001 Report	Flat fee	1,500.-
▪ ISO 15378 Report	Flat fee	1,620.-
▪ ISO 13485 Report	Flat fee	1,830.-
▪ TCP III Report	Flat fee	2,760.-
▪ Combined System Assessment Report	Flat fee	2,920.-
▪ Unannounced Audit Report	Flat fee	1,400.-
▪ Other System Assessment or Evaluation Report		Effort based
▪ Involvement of external clinical experts (Price incl. reporting with test duration of 1 PD. Additional services to be provided will be charged at 345€ / hour.)		4,320.-
▪ Handling of vigilance cases	Per case	100.-

Service & Additional Fees

Service Fee

- 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.
- The amount of the fee depends on the number of employees and locations covered by the certificate(s)

▪ Total number of employees	▪ Service basic amount		▪ Flat rate annual service hours
	▪ Normative certification	▪ Regulatory certification	
▪ 1 – 45	▪ 500 €	▪ 1.830 €	▪ 4 Hours
▪ 46 – 625	▪ 1.300 €	▪ 2.920 €	▪ 8 Hours
▪ > 625	▪ 2.370 €	▪ 5.620 €	▪ 16 Hours

(Should the included flat-rate annual service hours be exceeded, additional hours will be charged at a rate of 345 euros per hour.)

▪ Service fee – certification committee		Effort based
▪ Service package according to individual needs (additopnal to general service fees)	Hourly	345.-
▪ Regulatory letter, change of a certificate (Typo, etc.)	Flat	345.-
▪ Consultation with medicinal product authorities	Hourly	345.-
▪ Assessment of changes	Hourly	345.-
▪ Planning meeting on site at the customer (The costs are per DQS MED participant and per hour or part thereof. Please note additional travel expenses.)	Hourly	345.-
▪ Membership MED Xpert Lab (mostly in German language; Annual subscription to a webinar expert series on regulatory topics with at least 10 dates per year.)		
For DQS customers		400.-
Standard fee:		990.-
▪ Translations of assessment and test reports		
Up to 10 pages 600 €, beyond that each additional page 30 €.		
▪ Special procedures	Hourly	345.-
▪ Structured Dialogue		Effort based
<small>(hourly 420,-/ additional charges may apply depending on the required effort, preparation time, number of experts involved, and other relevant factors.)</small>		

Certificates and attestations

The issuance of a certificate or attestation requires the positive completion of the underlying assessment.

▪ Certification fees		
ISO 9001	Per Year	590.-
ISO 13485	Per Year	1,150.-
ISO 15378	Per Year	1,150.-
TCP III	Per Year	1,200.-
MDSAP	Per Year	1,200.-
MDR (EU) 2017/745	Per Year	1,200.-
MDD (93/42/EEC) / Confirmation Letter according to Regulation EU 2023/607	Per Year	1,200.-
▪ Issuance of excerpt certificates as well as changes	Per page	140.-
▪ Issuance of additional language variants (GER, EN) <small>(Please note that in the event of changes to the underlying certificates and attestations, issued language variants must also be reissued.)</small>	Per page	140.-
▪ List of other language variants <small>(Please note that in the event of changes to the underlying certificates and attestations, issued language variants must also be reissued.)</small>		Effort based
▪ Notarization of a certificate		380.-
▪ Certificate apostille		500.-
▪ Adaptation Confirmation Letter according to Regulation EU 2023/607		1,200.-
▪ Content confirmation or supplementary letters		300.-
▪ Your company logo on your certificate	Per logo	115.-
▪ Personal certificate handover by DQS representative <small>(Please note additional travel expenses.)</small>		Effort based
▪ Printing and sending certificates and attestations		50.-
▪ Printing and sending certificates and attestations with original signature		180.-
▪ Publication on DQS Homepage		Included
▪ Cancellation and termination of pending assessments		Effort based
▪ Cancellation and termination of regulations of existing certificates and regulations		390.-
▪ Database entries, registrations (DMIDS, EUDAMED, MDSAP REP-s, etc.)		
Initial registration (initial or re-certification)	Hourly	345.-
In the course of a notifiable change, each		140.-
Customer initiated notifications		Effort based

Incidental costs

<ul style="list-style-type: none"> ▪ Travel times 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 24 hours, per one-way trip. 	Per hour	145.-
<ul style="list-style-type: none"> ▪ Mileage allowance 	Per km	0,75.-
<ul style="list-style-type: none"> ▪ Transportation 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. 	Effort based	
<ul style="list-style-type: none"> ▪ Accommodation We ask that you provide or reserve a reasonable, nearby place for the auditor(s) to stay overnight. 	Effort based	
<ul style="list-style-type: none"> ▪ Expenses 	Not charged	

*PD = person day

About this price list

Valid from 01.01.2026. 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.

Leveraging
Quality, Driving
Success.



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