

	Price List - Certification according to Regulation (EU) 2017/745 (MDR) & Recognition in Third Countries	010/12.2025
		ID: 5172

1. Certification Costs

Information

Basic information about the requirements of the procedure	free of charge
Issuing a quotation	free of charge

Application

Application fee (planning of certification cycle, project plan, creation of sampling plan and audit program, resource allocation) depending on complexity	min. 1.000,00 €
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Capped in accordance with the EU Commission Recommendation of 6 May 2003 concerning the definition of micro/small and medium-sized enterprises (SMEs) (2003/361/EC)

- Companies in size-class 2 (small enterprise) and 3 (microenterprise)	max. 5.000,00 €
- Companies in size-class 1 (medium-sized enterprise)	max. 10.000,00 €
- Companies that do not meet the definition of microenterprises, small or medium-sized enterprises (SMEs)	max. 15.000,00 €

The fee and maximum amounts apply per company and certification cycle

Assessment / Project management

The time required for each certification is determined individually, based on available guidelines. The following services will be charged within the context of initial certification/re-certification and planned or extraordinary surveillance:

- Assessment of QM-documents including report
- Assessment of technical documentation including report
- On-site audit (if necessary additional audits at subcontractors and suppliers)
- Audit planning and audit report
- Assessments in consequence of notifications of changes/extension applications
- Validation and upload (EUDAMED) of summaries of safety and clinical performance (SSCP)
- Assessment of periodic safety update reports (PSUR)
- Conducting consultation procedures with Authorities, EMA, Expert panels, Expert Laboratories of the EU Commission according Art. 106 of MDR
- Extraordinary time for assessment and administration expenses

Billing is according to the time consumption based on a daily rate of	2.400,00 €
for procedures accord. to Art. 16 MDR in connection with EN ISO 13485 a reduced daily rate of	2.000,00 €

Issue of certificates

- Fee for initial certification/re-certification (MDR) – per certificate	1.000,00 €
- Fee for amendments/extensions/changes (MDR) – per certificate	500,00 €
- Fee for initial certification/re-certification for each QM standard	500,00 €
- Fee for amendments/extensions/changes (EC Directive/QM standards)	250,00 €

Each mdc certification fee includes 1 certificate size 29,7 x 21,0 cm and as a PDF file in German or English language.

- Fee for initial certification/re-certification under MDSAP by DQS Medizinprodukte GmbH (per individual audit report)	2.000,00 €
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Each DQS certification fee includes 1 certificate as a PDF file in English language.

Annual certification fee (starting 1 year after initial certification/re-certification)

- Fee per year and certificate (MDR)	1.000,00 €
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Capped in accordance with the EU Commission Recommendation of 6 May 2003 concerning the definition of micro/small and medium-sized enterprises (SMEs) (2003/361/EC)

- Companies in size-class 2 (small enterprise) and 3 (microenterprise)	max. 5.000,00 €
- Companies in size-class 1 (medium-sized enterprise)	max. 10.000,00 €
- Companies that do not meet the definition of microenterprises, small or medium-sized enterprises (SMEs)	max. 15.000,00 €

- Fee per year for EC Directive	950,00 €
- Fee per year for each QM standard	400,00 €
- Fee per year under MDSAP by DQS Medizinprodukte GmbH (per individual audit report)	2.000,00 €

Unannounced Audits

- Fee for on-site audit (up to 2.0 auditor days)	4.800,00 €
- Fee for preparation and reporting (for up to 2.0 days on site)	3.000,00 €
- Fee for additional days on site (per day)	2.400,00 €
- Fee for report preparation for additional days on site (per day on site)	1.200,00 €

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Consultation procedures

- Fees of the competent body, e.g. external costs + 10%
 - Authorities, EMA
 - Expert panels, Expert Laboratories of the EU Commission according Art. 106 of MDR

Product testing

- At the manufacturer's premises as part of an unannounced audit free of charge
- At the manufacturer's premises as part of a technical file review as required – daily rate 2.400,00 €
- At subcontracted laboratories (including organization and administrative handling) external costs + 20%

Audit report for submission during approval in Taiwan

- As part of the "Technical Cooperation Programme on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports" issued Audit report, certificate ISO 13485 (size 29,7 x 21,0 cm), cover letter. 1.000,00 €
 +
 Translation costs in accordance with section 3
- The fee is due at the beginning of a period of three years and includes the items only once.
 In case further reports are required, the same fee is due again.

Recognition by cooperation partners in Ukraine

- Initial confirmation per manufacturer 1.000,00 €
- Further services (e.g. confirmations, correspondence, administration) are charged as required on the basis of a daily rate of 2.400,00 €

2. Travel expenses and travel times

- Related travel to the main audit location and other customer locations in Germany or Austria within a radius of 100 km for certification and surveillance audits: € 150,00
 Travel allowance per audit day and auditor on site

Other travel costs and travel time inside of Germany / Austria to further audit sites and travelling for the purpose of on-site review of documents, follow-up audits, supplier audits, product testing or other special occasions as well as all travel costs and travel times to audit sites outside Germany / Austria:

- Car transport based on driven distance per km 0,40 €
- Flight: business class ticket costs, train: first class ticket costs, taxi/rental car/road fees/parking fees etc. as required
- Travel times per started hour 120,00 €
- Accommodation (hotel costs) as required

3. Special services

- Certificates in additional languages** (German or English) size 29,7 x 21,0 cm and as a file in PDF format 100,00 €

Additional originals of existing certificates size 29,7 x 21,0 cm per copy

- up to 10 copies 30,00 €
- up to 25 copies 20,00 €
- up to 50 copies 15,00 €
- from 51 copies on request

Additional originals of existing certificates size 42,0 x 29,7 cm per copy

- up to 10 copies 50,00 €
- from 11 copies on request

Subsequent change of address or scope

- after signing confirmation of audit data 150,00 €

Reinstatement of suspended certificates

250,00 €

- Issuing of additional attestations** if requested from client (additional assessment / administrative costs) 100,00 €

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Issuing of a report in English language (translation German > English) 1.500,00 €
up to 6000 words. After exceeding 6000 words costs vary based on the complexity.

Issuing of certificates with notarization/legal attestation

- first certificate with notarization 250,00 €
- further certificates with notarization at the same time 100,00 €
- first certificate with notarization and apostille 300,00 €
- further certificates with notarization and apostille at the same time 150,00 €

Integration of the client's logo into certificates in accordance with **QM Standards** according to a provided PNG file with alpha channel/transparency 100,00 €

Certification mark according QM Standards with mdc-logo by e-mail free of charge

4. Legal additional costs

For all services VAT as legally required applies.