	Price List - Certification according to Regulation (EU) 2017/746 (IVDR) & Recognition in Third Countries	005/06.2024
		ID: 9911

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 €
- Companies with up to 50 employees in the entire company	max. 5.000,00 €
- Companies with up to 250 employees in the entire company	max. 10.000,00 €
- Companies with more than 250 employees in the entire company	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 guidelines, if available. 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 performance (SSP)
- Assessment of periodic safety update reports (PSUR)
- Conduct of 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 IVDR in connection with EN ISO 13485 a reduced daily rate of	2.000,00 €

Issue of certificates

- Fee for initial certification/re-certification (IVDR) – per certificate	1.000,00 €
- Fee for amendments/extensions/changes (IVDR) – 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 €
- Fee for initial certification/re-certification under MDSAP by DQS Medizinprodukte GmbH	1.500,00 €

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

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

- Fee per year and certificate (IVDR)	1.000,00 €
- Companies with up to 50 employees in the entire company per year	max. 5.000,00 €
- Companies with up to 250 employees in the entire company per year	max. 10.000,00 €
- Companies with more than 250 employees in the entire company per year	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	1.500,00 €

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 €

Consultation procedures

- Fees of the competent body, e.g.	external costs + 10%
- Authorities, EMA	
- Expert panels, expert laboratories of the EU Commission according to 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) if not charged according Chapter 4	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. 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.	1.000,00 € + Translation costs in accordance with section 3

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

One time trip to the client’s main site located in Germany or Austria and further company sites of the client in a radius of 50 km for certification & surveillance audits as well as unannounced audits	free of charge
Other travel costs and travel time inside of Germany and 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 travel costs and travel times to audit sites outside Germany and 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 form client (additional assessment / administrative costs)	100,00 €
Issuing of a report in English language (translation German > English) up to 6000 words. After exceeding 6000 words costs vary based on the complexity.	1.500,00 €

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. Verification of manufactured products according to Regulation (EU) 2017/746 Annex IX Section 4.9 (performance study) resp. Section 4.12 (batch release) of class D devices

Establishing of specific criteria for batch release on 3 batches as a preparation of the batch release per product:	
- Transmissible agents (immunoassays and NAT)	external costs + 800,00 €
- Blood grouping reagents immunological	external costs + 800,00 €
- Blood grouping reagents (other methods)	external costs + 800,00 €
- Modification of established criteria for batch testing	external costs + 600,00 €

Laboratory testing and assessment of the manufacturer's QC documents	
Screening tests (immunological and NAT for infection parameters) per batch	external costs + 600,00 €
Separately submitted controls and calibrators (infection parameters) per batch	external costs + 600,00 €
Blood grouping reagents (class D) immunological per batch	external costs + 600,00 €
Blood grouping reagents (class D) NAT per batch	external costs + 600,00 €
Multiplex NAT per batch	external costs + 600,00 €
Multiplex NAT with separate discrimination per batch	external costs + 600,00 €
Multi-analyte controls for NAT and immunoassays:	
- per batch	external costs + 600,00 €
Material costs incurred in the framework of the testing are calculated according to expenditure.	
Batch release based on document review following the prior testing of at least one product batch by an EURL	based on effort, at least 600,00 €

Assessment of documents, additional assessments	
Batch release based on document review (e.g. relabelling, shelf-life extension, additional trade names) per individual product or variant	600,00 €
Extraordinary additional assessments required (e.g. in connection with non-conforming batches or product changes). Invoiced according to the expenses incurred based on a daily rate of	2.400,00 €

5. Legal additional costs

For all services VAT as legally required applies.