mdc	Price List – Certification according to EC Directive 98/79/EC (IVDD)	006/06.2024 ID: 3219

1. Certification costs

Information	
Basic information about the requirements of the procedure and costs of a certification	free of charge
Issuing a quotation	free of charge
Application	
Application fee (only for initial certification)	250,00 €
Assessment / Project management	
The time required for each certification is determined individually, based on the international guidelines (IAF, Code of Conduct, MDSAP) The following services will be charged within the context of initial certification and surveillance: - assessment of QM documents and technical documentations - audit on site (if necessary additional audits at subcontractors and suppliers) - audit planning and audit report - extraordinary time for administration expenses	
Billing is according to the time consumption based on a daily rate of	1.590,00 €
Issue of certificates	
- Fee for initial certification/re-certification according to IVDD Directive	950,00 €
- Fee for amendments/extensions/changes in certification according to IVDD Directive	250,00 €
- Fee for initial certification/re-certification fee for each QM standard	500,00 €
- Fee for initial certification/re-certification under MDSAP by DQS Medizinprodukte GmbH	1.500,00 €
Each certification fee includes one certificate 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)	
- Annual certification fee for IVDD Directive	950,00 €
- Annual certification fee for each QM standard	400,00 €
- Annual certification fee under MDSAP by DQS Medizinprodukte GmbH	1.500,00 €
Unannounced audits	
- Fee for on-site audit (up to 2.0 auditor days)	3.180,00 €
- Fee for preparation and reporting (for up to 2.0 days on site)	1.810,00 €
- Fee for additional days on site (per day)	1.590,00 €
- Fee for report preparation for additional days on site (per day on site)	795,00 €
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	1.590,00 €
- at subcontracted laboratories (including organization and administrative handling)	external costs+15%
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	1.590,00 €

2. Travel expenses and travel times

One time trip to the main site of an audit in Germany and further company sites of the client in a radius of 50 km for certification and surveillance audits as well as unannounced audits not related to specific events in Germany	free of charge
Other travel costs and travel time inside of Germany 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:	
- 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)	90,00 €
- Accommodation (hotel costs)	as required

3. Special services

Certificates in additional languages (German, English, French, Spanish, Italian) Size 29,7 x 21,0 cm with attached translation of the certification scope per language	100,00 €
Certificates in other languages (Certificates according to EC guidelines only in the official languages of the EU)	on request
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 and/or scope for certificates not yet issued after signing the confirmation of certification data	150,00 €
Reinstatement of suspended certificates	250,00 €
New certificate for change of company name or change of address (for each company and certificate; additional assessment if necessary)	150,00 €
Issuing of specific certificate appendices and additional attestations if requested from client (additional assessment if necessary; per appendix/attestation)	80,00 €
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 €
Certificates with notarization/legal attestation	
- first certificate with notarization	250,00 €
- further certificates with notarization at the same time	150,00 €
- first certificate notarization and apostille	300,00 €
- further certifications with notarization and apostille at the same time	180,00 €
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 Annex IV.6 or Annex VII.5 (batch release) for devices according to Annex II, List A of Directive 98/79/EC on in vitro diagnostic medical devices

Establishing of specific criteria for batch testing on 3 batches as a preparation of the verification of manufactured products per product:	
- List A virus marker (immunoassays and NAT)	3.200,00 €
- List A blood grouping reagents immunological	2.350,00 €
- List A blood grouping reagents NAT	3.200,00 €
- Modification of established criteria for batch testing	420,00 €
Laboratory testing and assessment of the manufacturer's QC documents	
Screening tests (Anti-HIV, Anti-HCV, HBsAg, Anti-HBc, Anti-HTLV I and II and NAT) per batch	1.720,00 €
Non-screening tests (viral markers according to Annex II, List A) per batch	1.280,00 €
Separately submitted controls and calibrators (viral markers according to Annex II, List A) per batch	530,00 €
Blood grouping reagents (AB0-System, Rhesus, Kell-system) immunological per batch	1.080,00 €
Blood grouping reagents (AB0-System, Rhesus, Kell-system) NAT per batch	1.280,00 €
Rapid tests (acc. table 3 CTS) per batch	1.280,00 €
Multiplex NAT per batch	2.500,00 €
Multiplex NAT with separate discrimination per batch	3.150,00 €
Multi-analyte controls for immunoassays and NAT:	
- 1 marker List A per batch	630,00 €
- 2-3 markers List A per batch	950,00 €
- from 4 markers List A per batch	1.780,00 €
Material costs incurred in the framework of the testing are calculated according to expenditure.	
Assessment of the manufacturer's QC documents (without laboratory testing)	
Per batch.	355,00 €
Additional assessments	
Extraordinary additional required assessments (e. g. related to non-conforming batches or device changes) per day	1.590,00 €
Product testing in subcontracted laboratories (including organization and management).	external costs +15%
Confirmations	
Issuing of OEM confirmations; per confirmation	130,00 €
Issuing of confirmations of shelf life extension; per confirmation	95,00 €
(on the basis of existing reports and batch release confirmations for identical products)	

5. Legal additional costs

For all services VAT as legally required applies.