Medical Devices

Price list for services | valid as of October 27, 2025 | Version 3.0

List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745) and IVDR (2017/746), Notified Body TÜV Rheinland LGA Products GmbH (NB 0197)*

	TYPE OF FEE	FEE (EUR)	FACTORS INFLUENCING THE CALCULATION OF FEE CHARGED	FEE RANGE (MIN–MAX)
Administrative charges				
Application fee	Flat	2.480€	Quality of submission, maturity of QMS	2.480€
Administrative fee related to changes	Notification	400€	Number and complexity of changes	Basis rate/change: 400€
Annual certificate maintenance fee	Flat	2.410€	Number of sites, technical documentations, MDS codes and sterilization methods covered by the project	2.410€–15.000€
Certification fee	Flat	3.450€	Number of sites, technical documentations, MDS codes and sterilization methods covered by the project	3.450€–15.000€
Travel time costs (excluding expenses such as hotel costs)	Hourly	160€	Travel duration to audit sites	160€
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	310€	Number and complexity of external services	310€
Auditing				
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	310€	Number of FTEs and sites, non-conformities in last audit, factors for increase or decrease of audit duration	2.480€–55.800€
Unannounced Audit	Hourly	310€	Number of assessors on site (min. 2 auditors 1 day)	4.960€–20.460€
Product testing				
Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	200€	Characteristics and complexity of the device	200€

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	TYPE OF FEE	FEE (EUR)	FACTORS INFLUENCING THE CALCULATION OF FEE CHARGED	FEE RANGE (MIN–MAX)
Documentation Review				
Technical documentation assessment	Hourly	410€	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	9.840€–78.720€
Clinical evaluation report assessment (CEAR)	Hourly	430€	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	3.440€–52.000€
Expert panel consultation	Hourly	430€	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	3.440€–52.000€
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	430€	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	430€–2.500€
Consultation with medicinal product authorities[5]	Hourly	430€	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	430€–20.000€
Consultation with human tissue and cells competent authority	Hourly	430€	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	430€–35.000€
Consultation with the coordinating competent authority for devices utilizing animal tissues	Hourly	430€	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	430€–35.000€
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	410€	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	410€–2.500€
Assessment of changes	Hourly	410€		410€–15.000€
Reporting (if not covered above)				
	Hourly	410€	Number of FTEs and sites	2.480€–24.800€

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Miscellaneous Fees for Conformity Assessment Activities

SERVICE	DESCRIPTION	STANDARDS AND REGULATIONS	HOURLY RATE/COSTS PER TRANSACTION
Additional Effort Audit	Audit services that cannot be planned in advance due to circumstances for which we are not responsible will be charged on a time and material basis per hour incurred. If the additional effort exceeds 3 person days per process, you will receive an additional offer, e.g. repetitions of document reviews, increase of planned audit times, evaluation of corrective actions and significant change notifications to the QM system, authority inquiries, answering of technical questions by phone, e-mail or meetings, follow-up audits or additionally required audits at your premises and those of your suppliers.	ISO 15378:2017 MDSAP Travel time	210€ 300€ 160€
Ukraine Cover Letter (annual)			1.950€
Issuance and License Fee for Taiwan (TCP Cover Letter)			1.950€
MDSAP certificate		Basic fee 1.500€ plus 200€ per country Initial certification Basic fee 1.000€ plus 200€ per country Annual license fees	
eCertificates	Certificates signed purely digitally, per scheme and language; dispatch as pdf	Currently only possible in English	90€
Technical Meeting		TD relevant content Audit relevant content	410€/h/per Auditor 310€/h/per Auditor
Significant Change Notification (SCN) Preliminary assessment by the auditor and the certification body	Preliminary assessment SCN Upon receipt of an SCN, an invoice for 4h is automatically sent for the pre-assessment by the auditor and the certification body.	TD relevant changes Audit relevant changes	410€/h 310€/h

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SERVICE	DESCRIPTION	STANDARDS AND REGULATIONS	HOURLY RATE/COSTS PER TRANSACTION
Significant Change Notification (SCN)	Final evaluation by the auditor	TD relevant changes (MDR) Audit relevant changes (MDR)	410€/h 310€/h
		TD relevant changes (IVDR) Audit relevant changes (IVDR)	410€/h 310€/h
	Evaluation by the certification body Re-issue SX-Certificate Re-issue MDR certificate (QM) Re-issue IVDR Certificate (QM)		500€ 500€ min. 1.250€ min. 1.310€
Legalization through an embassy	Prerequisite: notarized certificate (duplicate), apostille by the notary public. Per certificate type and with the involvement of the company ‚Docu – Legal; Owner: A. Ababneh, Berlin' (service provider legalizations) Costs according to expenditure [For countries outside the Hague Convention possible further costs arise].	Per type of certificate	150€
Certificate issuance in other languages	French, Spanish, Italian [Certificate issuance in all other languages, at cost]		140€/Certificate
Authentication certificate copy	Including preparation of duplicate, internal coordination, notary fees		250€
Preparation of an apostille	Including preparation of duplicate, internal coordination, notary fees, district court costs		500€