

Price list for services

including MDR/IVDR | valid as of October 1, 2024 | Version 2.0

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.	EN ISO 13485:2021 / ISO 9001:2015	190€
		EN ISO 13485:2021 KRINKO-BfArM	210€
		ISO 15378:2017	210€
		MDSAP	300€
		MDR 2017/745	300€
		IVDR 2017/746	310€
		Travel time	160€
Unannounced Audit	At least one day with two auditors on-site such as three days for preparation and assessment including issuance of audit documentation such as administrative and certification-related activities (excluding travel times and expenses).	MDR 2017/745 IVDR 2017/746	300€ 310€
Additional Effort Review Technical Documentation	Product-related services that cannot be planned in advance due to circumstances beyond our control 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. increased review effort of the technical documentation due to higher complexity of the product (e.g. system or kit character), additional review rounds of the technical documentation, significant change notifications for products, processing of incident reports, technical meetings with product reference.	MDR 2017/745	398€
		IVDR 2017/746	410€
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	

SERVICE	DESCRIPTION	STANDARDS AND REGULATIONS	HOURLY RATE / COSTS PER TRANSACTION
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 TD relevant content Audit relevant content	390€/h/per Auditor (MDR) 300€/h/per Auditor (MDR) 410€/h/per Auditor (IVDR) 310€/h/per Auditor (IVDR)
Significant Change Notification (SCN) Preliminary assessment by the auditor and the certification body	Preliminary assessment SCN	TD relevant changes Audit relevant changes	398€/h (MDR) 300€/h (MDR)
	Preliminary assessment SCN	TD relevant changes Audit relevant changes	410€ (IVDR) 310€ (IVDR)
	Upon receipt of an SCN, an invoice for 4h is automatically sent for the pre-assessment by the auditor and the certification body.		
Significant Change Notification (SCN)	Final evaluation by the auditor	TD relevant changes (MDR) Audit relevant changes (MDR)	398€/h 300€/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 typ of certificate	150€
	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].		
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€