

List of Standard Fees (USD) for Conformity Assessment and Certification Activities under the MDR (2017/745), EN ISO 13485, MDSAP and TCP III Taiwan

NB 0482 • DNV MEDCERT GmbH

Service	Type of Fee	Factors influencing the calculation of fee charged ¹	Fee range
Application management fee for initial conformity assessment according to the MDR 2017/745	Flat	---	6.000 USD
Application fee for the Confirmation Letter related to the framework of Regulation 2023/607 ²	Flat	---	1.200 USD
QM Certification (incl. Project management)	Hourly	<ul style="list-style-type: none"> The size of the company The number and the complexity of the device(s) The number of non-conformities arising from the assessment(s) The number of assessment rounds 	360 USD/h
Unannounced Audit (2 auditors for 1 day, incl. preparation and reporting)	Flat	---	11.500 USD
Technical Documentation Assessment (incl. e.g. Assessment of changes, CEAR, Biocompatibility, Project management)	Hourly	<ul style="list-style-type: none"> The complexity of the device The number of non-conformities arising from the assessment(s) The number of assessment rounds 	395 USD/h
Confirmation of a written agreement according to Article 97 MDR	Flat	---	720 USD
Confirmation of products certified	Flat	---	480 USD
General letter of confirmation	Flat	---	240 USD
Annual license fee for each certificate according to the Medical Device Regulation 2017/745	Flat	Micro-enterprise ³	1.550 USD
		Small enterprise ³	1.850 USD
		Medium-sized enterprise ³	2.150 USD
		Enterprise ⁴	2.350 USD
Annual service fee related to the framework of Regulation 2023/607 (Confirmation Letter) for QMS and for each class III Products	Flat	Micro-enterprise ³	1.550 USD
		Small enterprise ³	1.850 USD
		Medium-sized enterprise ³	2.150 USD
		Enterprise ⁴	2.350 USD
Annual service fee for the surveillance according to Article 120 MDR 2017/745 for each QMS and for each class III Products	Flat	Micro-enterprise ³	1.550 USD
		Small enterprise ³	1.850 USD
		Medium-sized enterprise ³	2.150 USD
		Enterprise ⁴	2.350 USD

¹ This list does not claim to be exhaustive

² Validity of Confirmation Letter in the Framework of Regulation 2023/607:

- a. 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental crowns, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors
- b. 31 December 2028, for class IIb devices other than those covered by point (a), for class IIa devices, and for class I devices placed on the market in sterile conditions or having a measuring function

³ Special conditions for manufacturers belonging to SMEs as defined in Commission Recommendation 2003/361/EC

⁴ Recommendation according to recommendation 2003/361/EC does not apply

Service	Type of Fee	Factors influencing the calculation of fee charged ¹	Fee range
Annual license fee for certificates according to ISO 13485	Flat	---	1.300 USD
Annual license fee for certificates according to MDSAP	Flat	---	2.300 USD
License fee for 3 years Attestation Letter for Taiwan (TCP III)	Flat	---	2.200 USD
Services related to EUDAMED	Hourly	---	335 USD
Assessment of the sterilization validation	Hourly	---	395 USD/h Min. 7.900 USD
Notarisation of 2 certificates	Flat	---	750 USD excluding fees
Further notarisations of certificates	Flat	---	40 USD/ certificate
Services related to change notifications	Hourly	---	min. 790 USD (395 USD/h)
Travel time costs (excluding travel expenses)	Hourly	---	200 USD/h
Travel expenses	---	---	as incurred
Assessment of vigilance data according to MDR 2017/745 Annex VII, 4.10	Flat	• 1-3 cases / quarter	360 USD/case
		• > 4 cases / quarter	240 USD/case ⁵
Evaluation/review of Periodic Safety Update Report (PSUR)	Hourly	---	395 USD/h
Validation of Summary of Safety and Clinical Performance (SSCP)	Hourly	---	395 USD/h
Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	---	395 USD/h
Expert panel consultation	Hourly	---	395 USD/h
Consultation with medicinal product authorities	Hourly	---	395 USD/h
Consultation with the coordinating competent authority for devices utilizing animal tissues	Hourly	---	395 USD/h
Additional certificates	Flat	---	20 USD/certificate

⁵ Starting from 4th Vigilance report submitted