

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

NB 0482 • DNV MEDCERT GmbH

Service	Type of Fee	Factors influencing the calculation of fee charged <sup>1</sup>	Fee range
Application management fee for initial conformity assessment according to the MDR 2017/745	Flat	---	4,500€
Application fee for the Confirmation Letter related to the framework of Regulation 2023/607 <sup>2</sup>	Flat	---	900€
QM Certification (incl. Project management)	Hourly	<ul style="list-style-type: none"> <li>The size of the company</li> <li>The number and the complexity of the device(s)</li> <li>The number of non-conformities arising from the assessment(s)</li> <li>The number of assessment rounds</li> </ul>	270 €/h (German Auditor)  165 €/h (China Auditor)
Unannounced Audit (2 auditors for 1 day, incl. preparation and reporting)	Flat	---	8,600€
Technical Documentation Assessment (incl. e.g. Assessment of changes, CEAR, Biocompatibility, Project management)	Hourly	<ul style="list-style-type: none"> <li>The complexity of the device</li> <li>The number of non-conformities arising from the assessment(s)</li> <li>The number of assessment rounds</li> </ul>	300 €/h
Confirmation of a written agreement according to Article 97 MDR	Flat	---	540 €
Confirmation of products certified	Flat	---	400 €
General letter of confirmation	Flat	---	200 €
Annual license fee for each certificate according to the Medical Device Regulation 2017/745	Flat	Micro-enterprise <sup>3</sup>	1,050 €
		Small enterprise <sup>3</sup>	1,250 €
		Medium-sized enterprise <sup>3</sup>	1,450 €
		Enterprise <sup>4</sup>	1,550 €
Annual service fee related to the framework of Regulation 2023/607 (Confirmation Letter) for QMS and for each class III Products	Flat	Micro-enterprise <sup>3</sup>	1,050 €
		Small enterprise <sup>3</sup>	1,250 €
		Medium-sized enterprise <sup>3</sup>	1,450 €
		Enterprise <sup>4</sup>	1,550 €
	Flat	Micro-enterprise <sup>3</sup>	1,050 €
		Small enterprise <sup>3</sup>	1,250 €

<sup>1</sup> This list does not claim to be exhaustive

<sup>2</sup> Validity of Confirmation Letter in the framework of Regulation 2023/607:

- 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
- 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

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

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

Service	Type of Fee	Factors influencing the calculation of fee charged <sup>1</sup>	Fee range
Annual service fee for the surveillance according to Article 120 MDR 2017/745 for each QMS and for each class III Products		Medium-sized enterprise <sup>3</sup>	1,450 €
		Enterprise <sup>4</sup>	1,550 €
Annual license fee for certificates according to ISO 13485	Flat	---	850 €
Annual license fee for certificates according to MDSAP	Flat	---	1,750 €
License fee for 3 years Attestation Letter for Taiwan (TCP III)	Flat	---	1,650 €
Services related to EUDAMED	Hourly	---	270 €/h
Assessment of the sterilization validation	Hourly	---	300 €/h min. 6,000 €
Notarisation of 2 certificates	Flat	---	580 € excluding fees
Further notarisations of certificates	Flat	---	30 €/certificate
Services related to change notifications	Hourly	---	min. 810 € (270 €/h)
Travel time costs (excluding travel expenses)	Flat	German Auditor travelling to China	1,295 €
		China Auditor travelling to China	645 €
Travel expenses	---	---	as incurred
Assessment of vigilance data according to MDR 2017/745 Annex VII, 4.10	Flat	• 1-3 cases / quarter	300 €/case
		• > 4 cases / quarter	200 €/case
Evaluation of Periodic Safety Update Report (PSUR)	Hourly	---	300 €/h
Validation of Summary of Safety and Clinical Performance (SSCP)	Hourly	---	300 €/h
Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	---	300 €/h
Expert panel consultation	Hourly	---	300 €/h
Consultation with medicinal product authorities	Hourly	---	300 €/h
Consultation with the coordinating competent authority for devices utilizing animal tissues	Hourly	---	300 €/h
Additional certificates	Flat	---	15 €/certificate