Medical Devices

Medical Device Coordination Group Document MDCG 2023-2 MDR form

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), effective 01.10.2024.

	TYPE OF FEE[1]	FEE (EUR)	FACTORS INFLUENCING THE CALCULATION OF FEE CHARGED[2]	FEE RANGE (MIN-MAX)[3]
Administrative charges				
Application fee	Flat	2.400 €	Quality of submission, maturity of QMS	2.400 €
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	300 €	Number and complexity of external services	300 €
Auditing				
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	300 €	Number of FTEs and sites, non-conformities in last audit, factors for increase or decrease of audit duration	2.400 € – 54.000 €
Unannounced Audit	Hourly	300 €	Number of assessors on site (min. 2 auditors 1 day)	4.800 € – 20.000 €
Product testing				
Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	200 €	Characteristics and complexity of the device	200 €

	TYPE OF FEE[1]	FEE (EUR)	FACTORS INFLUENCING THE CALCULATION OF FEE CHARGED[2]	FEE RANGE (MIN-MAX)[3]
Documentation Review				
Technical documentation assessment[4]	Hourly	398 €	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	9.552 € – 76.416 €
Clinical evaluation report assessment (CEAR)	Hourly	410 €	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	3.280 € – 52.000 €
Expert panel consultation	Hourly	410 €	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	3.280 € – 52.000 €
Validation of the Summary of Safety and Clinical Performance (SSCP)	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 € – 2500 €
Consultation with medicinal product authorities[5]	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 € – 20.000 €
Consultation with human tissue and cells competent authority[5]	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 € – 35.000 €
Consultation with the coordinating competent authority for devices utilizing animal tissues[5]	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 € – 35.000 €
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	398 €	Complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, and rounds of reviews needed	398 € – 2500 €
Assessment of changes	Hourly	398 €		398 € – 15000 €
Reporting (if not covered above)				
			Covered above	

[1] Please delete parts not applicable

[2] Based on the notified body's methodology for issuing quotations the relevant factors influencing the calculation should be indicate, for example the complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, number nonconformities raised and rounds of reviews needed. These factors should be sufficiently clear for manufacturers to be able to estimate the approximate fee.

[3] Range of expected fee to be paid: A minimum to maximum fee charged for the conformity assessment item. In special cases the fee can be different from the upper and lower limits indicated. For "flat fees" only to be filled if applicable.

[4] In case rates may differ for onsite and offsite assessments or because of any other factors, these different rates should be shown. In cases fees differ for different types of assessments these should be shown separately.

[5] If applicable, fees charged by the notified body for conducting consultations with the relevant authorities (e.g. EMA, National Competent Authorities) in addition to fees payable to the relevant competent authority being consulted.

[6] Notified bodies should give an indication on their policy how SMEs are taken into consideration when setting the fee for these companies.