Medical Devices

Medical Device Coordination Group Document MDCG 2023-2

List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745), Notified body SGS Fimko Ltd (NB 0598)

	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged	Fee range(min-max)
Administrative charges				
• Application fee	Flat	3500	No	N/A
• Application fee for extension of certification	Flat	1000	No	N/A
• Administrative fee related to changes	Flat	600	Fee charged if the change requires a decision to act on the certificate	N/A
• Annual certificate maintenance fee (provide details which activities covered)	Flat	4675	Add 600 € per technical documentation file	N/A
• Other (specify)	N/A	N/A	N/A	N/A
Travel time costs (excluding expenses such as hotel costs)	Hourly	132	Depending on local office and possibility to work during travel	N/A
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	N/A	N/A	N/A	N/A
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Daily	2800	Days based on IAF MD9	N/A
• Unannounced Audit	Daily	2800	2 auditors + review	N/A
Product testing				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Daily	2800	N/A	N/A
Documentation Review				
• Technical documentation assessment	Daily	3500	Duration depending on device class and characteristics	Typical minimum: Class I 2 d Class IIa 4 d Class IIb 5 d Class III 8 d
• Clinical evaluation report assessment (CEAR)	Daily	3500	Duration depending on	Typical 1 d
• Expert panel consultation	Flat	2000	N/A	N/A
• Validation of the Summary of Safety and Clinical Performance (SSCP)	Daily	3500		Part of TDA

	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged	Fee range(min-max)
• Consultation with medicinal product authorities	Flat	2000	N/A	N/A
• Consultation with human tissue and cells competent authority	Flat	2000	N/A	N/A
• Consultation with the coordinating competent authority for devices utilizing animal tissues	Flat	2000	N/A	N/A
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Daily	3500	Initial review of 1 day	N/A
• Assessment of changes	Hourly	350 or 437.50	Minor changes included in the annual fee. 350 €/h for changes that require QMS audits and 437.50 €/h for changes that require TDA.	N/A
Reporting (if not covered above)		N/A	N/A	N/A

Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	Audit days are calculated based on IAF MD9 guidelines, dependent on the FTE of the manufacturer