

Notified body SGS Fimko Oy (NB 0598)

Conformity Assessments Activities under the IVDR (2017/746)

List of Standard Fees

	Type of Fee ⁱ	Fee in local currency	Factors influencing the calculation of fee charged	Fee range (min-max)
Administrative charges				
• Application fee	Flat	3,500 EUR	No	N/A
• Administrative fee related to changes	Flat	1000	No	N/A
• Annual certificate maintenance fee (please give details of activities covered)	Flat	800 – 1350	Depending upon the company size	N/A
• Other	N/A	N/A	N/A	N/A
Travel time costs	Hourly	138	Depending on local offices and possibility to work during travel	N/A
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	350 EUR	Sample collection at hourly rate 200 EUR + travel costs 0.5 EUR/km + postage and packing at real cost + laboratory costs	N/A
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	350 EUR	Audit days calculated as per IAF MD9 ¹ Calculation is influenced by the factors that may increase ² or reduce ³ duration of the audit.	N/A
• Unannounced Audit	Daily	2800 EUR	min. two auditor man days	N/A
Product testing				
• Laboratory testing for verification of performance (including preparation and reporting but excluding	Daily	2800	Testing in external laboratory, Direct costs from the testing laboratory	N/A

Medical Devices

	Type of Fee ⁱ	Fee in local currency	Factors influencing the calculation of fee charged	Fee range (min-max)
expenditures incurred for external tests)				
• Batch testing	Hourly	350	Testing in external laboratory, Direct costs from the testing laboratory	N/A
Documentation Review /Consultation				
• Technical documentation assessment ⁴	Daily	3500 EUR	per technical file (with one intended purpose), includes 2-3 rounds offsite.	14 000 – 45 000 Depending upon the risk class and devices
• Performance Evaluation Assessment Report (PEAR)	Hourly	350 EUR	per technical file (with 1 intended purpose), includes 2 rounds offsite.	N/A
• Expert panel consultation	Flat	Direct costs	+ min. 4 hrs of expert review with hourly cost	N/A
• Validation of the Summary of Safety and Performance (SSP)	Hourly	350 EUR	N/A	N/A
• Consultation of a medicinal product authority for a companion diagnostic	Hourly	Direct costs	+ min. 2 hrs of expert review with hourly cost	N/A
• Consultation of an EU reference laboratory for performance verification ⁵	Hourly	Direct costs	+ min. 2 hrs of expert review with hourly cost	N/A
• Consultation of an EU reference laboratory for batch testing	Hourly	Direct costs	+ min. 2 hrs of expert review with hourly cost	N/A
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	350 EUR	N/A	N/A
• Assessment of changes	Hourly	350 EUR	N/A	N/A
Reporting (if not covered above)	N/A	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.			

Note: Above mentioned prices are indicative. Number of submitted technical documentations, size of the company, number of locations or complexity of the product have impact on calculation of individual price offer.

The prices for the audit in Auditing section do not include travel and accommodation costs.

Prices does not include VAT.