

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	2500 EUR *)	Completeness and quality of the submission, manufacturer size.	N/A
• Administrative fee related to changes in certificates	Flat	650 EUR	No	N/A
• Annual certificate maintenance fee	Flat	2500 EUR	N/A	N/A
• Other	N/A	N/A EUR	N/A	N/A
Travel time costs	Hourly	145 EUR	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	364 EUR	+ travel costs 0.5 €/km + postage and packing at real cost + laboratory costs	N/A
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	364 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	2900 EUR	min. two auditor man days	N/A
Product testing				
• Laboratory testing for verification of performance (including preparation and reporting but excluding expenditures incurred for external tests)	Flat	1450 EUR	+ direct costs from the testing laboratory	N/A
• Batch testing	Hourly	364 EUR	+ direct costs from the testing laboratory	N/A
Documentation Review /Consultation				

Medical Devices

	Type of Fee ⁱ	Fee in local currency	Factors influencing the calculation of fee charged	Fee range (min-max)
• Technical documentation assessment	Daily	3650 EUR	per technical documentation (with one intended purpose), includes 2-3 review rounds.	3650 ~ 33 000 € Depending upon the risk class and devices
• Performance Evaluation Assessment Report (PEAR)	Hourly	364 EUR	min. 2 hrs of expert review per PEAR (with 1 intended purpose), includes 2 rounds offsite.	N/A
• Expert panel consultation	Hourly	364 EUR	min. 2 hrs of expert review + direct costs	N/A
• Validation of the Summary of Safety and Performance (SSP)	Hourly	364 EUR	min. 4 hrs of expert review	N/A
• Consultation of a medicinal product authority for a companion diagnostic	Hourly	364 EUR	min. 2 hrs of expert review with hourly cost + direct costs	N/A
• Consultation of an EU reference laboratory for performance verification	Hourly	364 EUR	min. 2 hrs of expert review with hourly cost + direct costs	N/A
• Consultation of an EU reference laboratory for batch testing	Hourly	364 EUR	min. 2 hrs of expert review with hourly cost + direct costs	N/A
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	364 EUR	min. 2 hrs of expert review	N/A
• Assessment of changes	Hourly	364 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	<p>) Discounted initial application fee for the manufacturers belonging to SME as defined in Recommendation 2003/361/EC (enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. Evidence of the SME status must be provided with the application. Fee for large manufacturers is 4.000 EUR.</p>			

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.