

List of Standard Fees for Conformity Assessment Activities under the IVDR (2017/746), Notified Body 1639 – SGS Belgium NV

All prices are minimum standard prices. Local Delivering Offices may add specific additional fees or costs for travel.

We will provide a specific service and fee proposal, tailored to your individual needs upon receipt of an application for services from you. For more details, please contact your local SGS Delivering Office.

Local taxes are payable in addition to our charges. Full details on charges will be set out in your service and fee proposal.

Our services are rendered in accordance with the terms of our Code of Practice, the rules governing the use of the SGS Certification Mark and SGS General Conditions for certification services. These can be found at <https://www.sgs.com/en/terms-and-conditions>.

	Type of Fee	Fee in Euros	Factors influencing the calculation of fee charged	Fee range (min-max)
Administrative charges				
Application fee	Flat	4,200.00	No	N/A
Administrative fee related to changes	N/A	None	No	N/A
Annual certificate maintenance fee	Flat	6,300.00	No	N/A
Other (specify)	N/A	N/A	No	N/A
Travel time costs (excluding expenses, such as hotel costs)	Hourly	210.00	Cost may change from local Medical Device Office	N/A
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Flat	2,625.00 315.00	Legal verification of certificate Regulatory letter	N/A
Auditing				
Audit (Certification, Recertification, Surveillance, Subcontractor / Supplier)	Daily	3,150.00		Based on IAF MD9 annexes
Unannounced Audit	Daily	3,150.00		At least 3 days
Product testing				
Laboratory testing for verification of performance (including preparation and reporting but excluding expenditures incurred for external tests)	Daily	3,150.00	N/A	N/A

	Type of Fee	Fee in Euros	Factors influencing the calculation of fee charged	Fee range (min-max)
Batch testing	N/A	N/A	IVDs requiring batch testing (Class D devices) are currently out of SGS NB 1639 designation scope	N/A
Documentation review				
Technical documentation assessment	Daily	3,885.00	Duration defined on device class and characteristics (IVS codes)	
Performance Evaluation Assessment Report (PEAR)	Daily	4,305.00	Duration defined on device class	
Expert panel consultation	Flat	2,100.00	No	No
Validation of the Summary of Safety and Performance (SSP)	Daily	3,885.00		Part of the Technical documentation assessment
Consultation of a medicinal product authority for a companion diagnostic	N/A	N/A	Companion diagnostic IVD medical devices are currently out of SGS NB 1639 designation scope	N/A
Consultation of an EU reference laboratory (EURL) for performance verification	N/A	N/A	Class D devices, involving EURLs for performance verification, are currently out of SGS NB 1639 designation scope	N/A
Consultation of an EU reference laboratory for batch testing	N/A	N/A	Class D devices, involving EURLs for batch testing, are currently out of SGS NB 1639 designation scope	N/A
Evaluation/review of the Periodic Safety Update Report (PSUR)	Daily	3,885.00	Initial review of 1 day and additional review	N/A
Assessment of changes	Hourly	388.50 or 493.50	388.50 Euros for change requested additional on-site audit 493.50 Euros for change requested with Technical Documentation Assessment	N/A
Reporting (if not covered above)	N/A	N/A	N/A	N/A



Special conditions for manufacturers belonging to SMEs as defined in Recommendation 2003/361/EC	On-site audit duration is calculated based on number of full-time employees.
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