List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745), 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 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	
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 (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)
Documentation review				
Technical documentation assessment	Daily	3,885.00	Duration defined on device class and characteristics (MDS codes)	
Clinical Evaluation Report Assessment (CEAR)	Daily	4,305.00	Duration defined on device class and CECP process	
Expert panel consultation	Flat	2,100.00	No	No
Validation of the Summary of Safety and Clinical Performance (SSCP)	Daily	3,885.00		Part of the Technical documentation assessment
Consultation with medicinal product authorities[1]	Flat	2,100.00	No	No
Consultation with human tissue and cells Competent Authority[1]	N/A	N/A	Human tissues are out of SGS designation scope	N/A
Consultation with the coordinating Competent Authority for devices utilizing animal tissues[1]	Flat	2,100.00	No	No
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.

[1] 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.