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 NB1639 (NB No.) – SGS Belgium NV

All prices are minimum standard prices. Local 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. Please, contact your local office for this.

Local taxes are payable in addition to our charges. Full details of 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	3,800	No	N/A
Administrative fee related to changes	N/A	None	No	N/A
Annual certificate maintenance fee (provide details of activities covered)	Flat	4,675	In addition: 600 Euros per technical documentation	N/A
Other (specify)	N/A	N/A	No	N/A
Travel time costs (excluding expenses, such as hotel costs)	Hourly	200	Cost may change from the local Medical Device Office	N/A
Administrative costs related to handling external services (laboratories, consultation or travel expenses)	Flat	2,000 300	Legal verification of certificate regulatory letter	
Auditing				
Audit (certification, re-certification, surveillance, subcontractor/supplier)	Daily	2,800		Based on IAF MD 9 annexes
Unannounced audit	Daily	2,800		At least 3 days
Product testing				
Laboratory testing (including preparation and reporting, but excluding expenditure incurred for external tests)	Daily	2,800	N/A	N/A
Documentation review				
Technical documentation assessment	Daily	3,500	Duration defined by device class and characteristics (MDS codes)	
Clinical evaluation report assessment (CEAR)	Daily	3,900	Duration defined by device class and CECP process	
Expert panel consultation[1]	Flat	2,000	No	No

	Type of fee	Fee in Euros	Factors influencing the calculation of fee charged	Fee range (min-max)
Validation of the Summary of Safety and Clinical Performance (SSCP)	Daily	3,500		Is part of the technical documentation assessment
Consultation with medicinal product authorities[1]	Flat	2,000	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	2,000	No	No
Evaluation/review of the Periodic Safety Update Report (PSUR)	Daily	3,500	Initial review of 1 day and additional review	N/A
Assessment of changes	Hourly	350 or 450	350 Euros for change requested and additional onsite audit. 450 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 SME, as defined in Recommendation 2003/361/EC	Onsite audit duration is calculated based on the 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.