Standard Fees for Conformity Assessment Activities Under the MDR (2017/745)

Notified Body 1639
SGS Belgium NV

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SGS Belgium NV (NB 1639) is committed to transparent and predictable pricing. Our local Delivering Offices, globally, may apply additional travel-related or statutory charges (such as local taxes), which will be clearly itemized in your personalized service and fee proposal.

Once we receive your application, we will create a tailored proposal designed around your specific MDR needs. For assistance, please reach out to your local Delivering Office.

All services are provided in line with our Code of Practice, SGS Certification Mark rules and the SGS General Conditions for Certification Services, available at https://www.sgs.com/en/terms-and-conditions.

In support of small and medium-sized enterprises (SMEs), as defined in Commission Recommendation 2003/361/EC, our fee structure is proportionate to the scale and complexity of the manufacturer's activities. This includes consideration of the number of full-time employees involved in medical device activities, virtual manufacturers, low-complexity operations and limited scopes of certification.

Audit duration is determined in line with applicable international guidance, including IAF MD9 (Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems – ISO 13485) and IAF MD5 (Determination of Audit time of Quality, Environmental, and Occupational Health & Safety Management Systems), taking into account the number of employees and the nature of the activities performed.

	Type of fee	**Fee in Euros**	**Factors influencing the calculation of fee charged**	**Fee range (min-max)**
Administrative charges				
Application fee	Flat	2,700	Maturity of QMS, completeness and quality of submission	≥2,700
Administrative fee related to changes	Flat	600	Maturity of QMS, completeness and quality of submission	≥600
Annual certificate maintenance fee	Flat	3,200	Number of FTEs	≥3,200
Other (specify)	N/A	N/A	N/A	N/A

	Type of fee	Fee in Euros	Factors influencing the calculation of fee charged	Fee range (min-max)
Travel time costs*	Daily	3,000*	Location of manufacturer	≥3,000
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	415	Completeness and quality of submission	415 - 600
Auditing				
Audit (certification, recertification, surveillance, subcontractor / supplier)*	Daily	2,500*	Number of FTEs, number of sites, numerous factors for audit increases or reductions	≥2,500
Unannounced audit*	Daily	5,000*	Number of auditors on site (minimum 2)	≥1.5 days
*Fee excludes expenses				
Product testing				
Laboratory testing for verification of performance (including preparation and reporting but excluding expenditures incurred for external tests)	Daily	3,950	Consult SGS for pricing	≥3,950

	Type of fee	Fee in Euros	Factors influencing the calculation of fee charged	Fee range (min-max)
Documentation review				
Technical documentation assessment	Daily	2,000	Device class and characteristics, completeness and quality of the submitted file	≥2,000
Clinical Evaluation Report Assessment (CEAR)	Daily	3,000	Duration defined on device class and CECP process	≥3,000
Expert panel consultation	Daily	3,100	Device class and characteristics, completeness and quality of the submitted file and authority fees	≥3,100
Validation of the Summary of Safety and Clinical Performance (SSCP)	Daily	3,100	Device class and characteristics, completeness and quality of the submitted file	≥3,100
Consultation with medicinal product authorities	Daily	3,100	Authority fees	≥3,100
Consultation with human tissue and cells Competent Authority	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	Daily	3,100	Authority fees	≥3,100
Evaluation/review of the Periodic Safety Update Report (PSUR)	Daily	3,100	Device class and characteristics, completeness and quality of the submitted file	≥3,100
Assessment of changes	Hourly	300 (Audits) 400 (TDA)	Type of change/s, completeness and quality of submission	≥300 ≥400
Reporting (if not covered)	N/A	N/A	Covered by Technical Documentation Assessment	N/A

Special conditions for manufacturers belonging to SMEs as defined in Recommendation 2003/361/EC	Factors in our fees are structured proportionally to the number of full-time employees involved in medical device activities including virtual manufacturer, low complexity activities and limited scope. Additionally, audit durations are determined based on the guidance in IAF-MD9 ["Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)"] and IAF-MD5 ["Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems"], factoring in the number of employees.

Contact our experts

Whether you are starting your journey, looking to transfer or wishing to discuss your exact needs, we are ready to help.

Speak with our experts

Request a quote

Or, visit our MDR Information Center

When you need to be sure

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