

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 0476 and 1912 (NB No)

	Type of Fee ¹	Fee in local currency	Factors influencing the calculation of fee charged ²	Fee range (min-max) ³
Administrative charges				
• Application fee	<u>Flat</u>	€ 3.000,-		
• Notification of change/certification changes	<u>Flat</u>	€ 800,-		
• Extension of certification	<u>Flat</u>	€ 1.500,-		
• Annual maintenance fee	<u>Flat</u>		SME or Non-SME	SME € 1.250,- Non-SME € 1.500,-
• Certification renewal fee	<u>Flat</u>	€ 3.000,-		
Travel time costs (excluding costs for travel and lodging)	<u>Hourly</u>	€ 150,-	Fees may vary due to currencies, travel policies and travel to specific geographies	
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	<u>Hourly</u>	€ 300		
• Unannounced Audit	<u>Daily</u>		1 day means 1 audit plus 1 reviewer	€ 5.600 – € 8.400
• Reporting (if not covered above)	<u>Hourly</u>	€ 300,-		
Documentation Review				
• Technical documentation assessment ⁴	<u>Hourly</u>	€ 400,-		
• Clinical data evaluation premarket and postmarket	<u>Hourly</u>	€ 400,-		
• Evaluation/review of the Periodic Safety Update Report (PSUR)	<u>Hourly</u>	€ 400,-		
Other services (when applicable)				
• Expert panel consultation ⁵	<u>Flat</u>	€ 1.600,- plus external costs		
• Validation of the Summary of Safety and Clinical Performance (SSCP)	<u>Hourly</u>	€ 400,-		
• Reporting (if not covered above)	<u>Hourly</u>	€ 400,-		

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<ul style="list-style-type: none"> • Consultation with medicinal product authorities⁵ 	<u>Flat</u>	€ 1.600,- plus external costs		
<ul style="list-style-type: none"> • Consultation with the coordinating competent authority for devices utilizing animal tissues⁵ 	<u>Flat</u>	€ 1.600,- plus external costs		
<ul style="list-style-type: none"> • Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests) 	<u>Flat</u>	At laboratory costs +15%		
Other				
Discount may be applicable, based on the countries policies.				
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC ⁶	Audit days, application and annual certificate maintenance fees are dependent on the FTE of the manufacturer. Annual maintenance fee is lower for SMEs			