

# 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 SGS Fimko Ltd (NB 0598) from 2026-03-01

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	<u>Type of Fee<sup>1</sup></u>	<u>Fee in EUROS</u>	<u>Factors influencing the calculation of fee charged<sup>2</sup></u>	<u>Fee range(min-max)<sup>3</sup></u>
<b>Administrative charges</b>				
• Application fee	Flat	2.500 *)	Completeness and quality of submission	From 2.500
• Application fee for extension of certification scope	Flat	1.000	Completeness and quality of submission	1.000
• Application fee for Article 16 certification	Flat	2.000	Completeness and quality of submission	2.000
• Administrative fee related to changes	Flat	600	Completeness and quality of submission. Additional assessment fees may apply for QMS and TD changes.	From 600
• Annual certificate maintenance fee	Flat	2.500		2.500
Travel time costs (excluding expenses such as hotel costs)	Hourly	145	Location of the manufacturer, possibility to work during travel	N/A
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly			
<b>Auditing</b>				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Daily	2.900	Days based on IAF MDs; factors for audit duration increases and reductions; planning and reporting	N/A
• Unannounced Audit	Daily	2.900	2 auditors + review	≥ 5.800
<b>Product testing</b>				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Daily	2.900	Required standards; laboratory testing fees	
<b>Documentation Review</b>				
• Technical documentation assessment <sup>4</sup>	Daily	3.650	Device complexity; completeness and quality of the submitted file	
• Clinical evaluation report assessment (CEAR)	Daily	3.650	Device complexity; completeness and quality of the submitted file	
• Expert panel consultation <sup>5</sup>	Flat	2.000	Excludes external fees	

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<ul style="list-style-type: none"> <li>Validation of the Summary of Safety and Clinical Performance (SSCP)</li> </ul>	Daily	3.650	Device complexity; completeness and quality of the submitted file	
<ul style="list-style-type: none"> <li>Consultation with medicinal product authorities<sup>5</sup></li> </ul>	Flat	2000	Excludes external fees	
<ul style="list-style-type: none"> <li>Consultation with human tissue and cells competent authority<sup>5</sup></li> </ul>	Flat	2000	Excludes external fees	
<ul style="list-style-type: none"> <li>Consultation with the coordinating competent authority for devices utilizing animal tissues<sup>5</sup></li> </ul>	Flat	2000	Excludes external fees	
<ul style="list-style-type: none"> <li>Evaluation/review of the Periodic Safety Update Report (PSUR)</li> </ul>	Daily	3.650		
<ul style="list-style-type: none"> <li>Assessment of changes</li> </ul>	Hourly	364 or 455	Depending on QMS of TD changes. Minor changes included in the annual fee. 364 €/h for changes that require QMS audits and 455 €/h for changes that require TDA.	
<b>Reporting (if not covered above)</b>		N/A	Covered in other fees	
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC <sup>6</sup>	*) Discounted fee for manufacturers that are eligible to the SME discount. Evidence of meeting the SME criteria are required in the application. Fee for large manufacturers is 4.000			

<sup>1</sup> Please delete parts not applicable

<sup>2</sup> Based on the notified body's methodology for issuing quotations the relevant factors influencing the calculation should be indicate, for example the complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, number nonconformities raised and rounds of reviews needed. These factors should be sufficiently clear for manufacturers to be able to estimate the approximate fee.

<sup>3</sup> Range of expected fee to be paid: A minimum to maximum fee charged for the conformity assessment item. In special cases the fee can be different from the upper and lower limits indicated. For "flat fees" only to be filled if applicable.

<sup>4</sup> In case rates may differ for onsite and offsite assessments or because of any other factors, these different rates should be shown. In cases fees differ for different types of assessments these should be shown separately.

<sup>5</sup> 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.

<sup>6</sup> Notified bodies should give an indication on their policy how SMEs are taken into consideration when setting the fee for these companies.