

Medical Devices

Medical Device Coordination Group Document

MDCG 2023-2 IVDR form

List of Standard Fees for Conformity Assessments Activities under the IVDR (2017/746)
Notified body XXXX (NB No)

	Type of Fee ⁱ	Fee in local currency	Factors influencing the calculation of fee charged ²	Fee range (min-max) ³
Administrative charges				
• Application fee	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Administrative fee related to changes	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Annual certificate maintenance fee (please give details of activities covered)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Other (specify)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
Travel timecosts (excluding expenses such as hotel costs)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Unannounced Audit	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
Product testing				
• Laboratory testing for verification of performance (including preparation and reporting but excluding expenditures incurred for external tests)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Batch testing	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
Documentation Review /Consultation				
• Technical documentation assessment ⁴	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Performance Evaluation Assessment Report (PEAR)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Expert panel consultation ⁵	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Validation of the Summary of	<u>Flat</u> <u>Hourly</u>			

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	<u>Type of Fee</u> ⁱ	<u>Fee in local currency</u>	Factors influencing the calculation of fee charged ²	Fee range (min-max) ³
Safety and Performance (SSP)	<u>Daily</u>			
• Consultation of a medicinal product authority for a companion diagnostic ¹	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Consultation of an EU reference laboratory for performance verification ⁵	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Consultation of an EU reference laboratory for batch testing ⁵	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Evaluation/review of the Periodic Safety Update Report (PSUR)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
• Assessment of changes	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			
Reporting (if not covered above)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>			

¹Please delete parts not applicable

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² Based on the notified body’s methodology for issuing quotations the relevant factors influencing the calculation should be indicated, 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.

³Range 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.

⁴ 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.

⁵ If applicable, fees charged by notified bodies for conducting consultations with the relevant authorities / expert panels / EU reference laboratories, in case notified body charges fees in addition to fees payable to the consulted bodies

⁶ Notified bodies should give an indication in their policy as to how the interests of SMEs are taken into consideration when setting the fees for these companies.

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Special conditions for
manufacturers belonging to SME
as defined in Recommendation
2003/361/EC⁶