List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745), according MDCG 2023-2 HTCert (NB 2803)

	Type of Fee	Fees (€)	Factors influencing the calculation of fee charged	min. - max
Administrative charges				
Application fee	Hourly	250	Calculated based on the type of the activity (e.g., initial certification, renewal, transfer or modification), the number and complexity of products, the size of the company and the complexity of the logistics. SME discounts apply.	Min: 2.000€ - Max: 12.000
Administrative fee related to changes	Hourly	250		
Annual certificate maintenance fee	Flat	≥7.000	Fee depends on the size of the company and the complexity of the logistics. SME discounts apply.	Min: 7.000€ - Max: 13.000
Certificate issuance	Flat	1.000	Fee per certificate issued, either initial certification or re-certification	
Other administrative costs	Hourly	250	Additional fees from third parties (e.g. Interpretation, Notarization of documents etc.)	
Travel time costs (excluding expenses such as hotel costs)	Daily	800		
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	250		
Auditing				
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	250	Calculated based on IAF MD-9 by applying several increasing and decreasing factors.	
Unannounced Audit	Flat	7.000		

Product testing				
Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	250	The calculation of handling costs is based on the number of products and the type of tests.	Min:1.000€ - Max: 4.000
Documentation Review				
Technical documentation assessment	Hourly	250	Factors taken into account in the calculation include complexity of the device, sterility, presence of medicinal substances or substances falling under rule 21, software incorporation, similarity to previous reviewed devices, and whether it is an initial certification or recertification assessment.	Min: 8.000€ - Max: 46.000
Clinical evaluation report assessment (CEAR)	Hourly	250	Part of the technical documentation assessment	The cost is included in the Technical Documentation assessment (see above).
Expert panel consultation	Hourly	250	Completeness and quality of submitted documents	
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	250	Completeness and quality of submitted documents	
Consultation with medicinal product authorities	Hourly	250	Fees determined by the authority consulted, Completeness and quality of submitted documents	
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	250	Completeness and quality of submitted documents	
Assessment of changes	Hourly	250	Type / Complexity of the change	Min: 1.000€ - Max: 6.000
Reporting (if not covered above)	Covered above	-		
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	Application fee: discount 20% Annual certificate maintenance fee: discount 10%			