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

	Type of Fee	Fees (€)	Factors influencing the calculation of fee charged
Administrative charges			
Application fee	Hourly	250€ *Min:1.000€ - Max: 15.000*	Fee depends on number & classification of products, complexity, company size
Administrative fee related to changes	Hourly	250€	
Annual certificate maintenance fee (issuance, administration)	Flat	1.000€ per certificate issuance 3.650€ annual certification fees	
Other, APOSTILE	Flat	External cost + 10%	
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)	Flat	Product testing at the manufacturer's premises: no additional charge. Product testing at subcontracted laboratories: external cost + 10% for handling costs.	
Documentation Review			
Technical documentation assessment	Hourly	250€	Calculated based on risk classification by applying several increasing and decreasing factors.
Clinical evaluation report assessment (CEAR)	Hourly	250€	Calculated based mainly on risk classification
Expert panel consultation	Flat	1000€	Per product
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	250€	

Consultation with medicinal product authorities	Hourly	250€ (Min 1000€)	
Consultation with human tissue and cells competent authority	N/A	N/A	N/A
Consultation with the coordinating competent authority for devices utilizing animal tissues	N/A	N/A	N/A
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	250€	
Assessment of changes	Hourly	250€	
Reporting (if not covered above)	covered above		
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	**Application fee:** • Max 4.000€ for micro (<10) • Max 8.000€ for small (<50) • Max 12.000€ for medium (<250)		