

List of Standard Fees for Conformity Assessment Activities under the MDR
(2017/745), Notified body CE CERTISO KFT (NB 2409)

	Type of Fee ⁱ	Fee	Factors influencing the calculation of fee charged	Fee range
Administrative charges				
• Application fee	Flat	1.000 €	-	1.000 €
• Administrative fee related to changes	Hourly	250 €	-	min 500 €
• Annual certificate maintenance fee (provide details which activities covered)	Flat	500 €	-	500 €/year
• Other - certificate issue fee	Flat	120 €	-	120 €
Travel timecosts (excluding expenses such as hotel costs)	Hourly	100 €	-	100 €/h
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	100 €	-	100 €/h
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	250 €	<ul style="list-style-type: none"> • The number of employees • The number of sites 	250 €/h
• Unannounced Audit	Hourly	250 €	-	min 7.200 € + travel cost and travel timecost
Product testing				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	N/A	N/A	-	N/A
Documentation Review				
• Technical documentation assessment ⁱⁱ	Hourly	250 €	<ul style="list-style-type: none"> • The complexity of the device • The number of assessment rounds 	250 €/h
• Clinical evaluation report assessment (CEAR)	Hourly	250 €		250 €/h
• Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	250 €		250 €/h
• Consultation with medicinal product authorities ⁵	Hourly	250 €		250 €/h
• Consultation with human tissue and cells competent authority ⁵	Hourly	250 €		250 €/h
• Consultation with the coordinating competent authority for devices utilizing animal tissues ⁵	Hourly	250 €		250 €/h
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	250 €		250 €/h
• Assessment of changes	Hourly	250 €		250 €/h
Reporting (if not covered above)	Flat Hourly Daily	N/A	-	N/A