

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

	Type of Feeⁱ	Fee	Factors influencing the calculation of fee charged	Fee range
Administrative charges				
• Application fee	<u>Flat</u>	3.000 € SME ¹ : 2.000 €	-	3.000 € SME ¹ : 2.000 €
• Administrative fee related to changes	<u>Hourly</u>	250 €	-	min 500 €
• Annual certificate maintenance fee (provide details which activities covered)	<u>Flat</u>	500 €	-	500 €/year
• Other - certificate issue fee	<u>Flat</u>	120 €	-	120 €
Travel timecosts (excluding expenses such as hotel costs)	<u>Hourly</u>	175 € SME ¹ : 150 €	-	175 € SME ¹ : 150 €/h
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	<u>Hourly</u>	150 €	-	150 €/h
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	<u>Hourly</u>	250 €	<ul style="list-style-type: none"> • The number of employees • The number of sites 	250 €/h
• Unannounced Audit	<u>Hourly</u>	250 €	-	min 7.200 € + travel cost and travel time cost
Product testing				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	<u>N/A</u>	N/A	-	N/A
Documentation Review				
• Technical documentation assessment	<u>Hourly</u>	250 €	<ul style="list-style-type: none"> • The complexity of the device • quality and structure of TD 	250 €/h min 5.000 €- max 60.000 €
• Clinical evaluation report assessment (CEAR)	<u>Hourly</u>	250 €		250 €/h min 2.500 €- max 15.000 €
• Validation of the Summary of Safety and Clinical Performance (SSCP)	<u>Hourly</u>	250 €		250 €/h min 2.000 €- max 8.000 €
• Consultation with medicinal product authorities ²	<u>Hourly</u>	250 €		250 €/h min 6.000 €- max 12.000 €
• Consultation with human tissue and cells competent authority ²	<u>Hourly</u>	250 €		250 €/h min 6.000 €- max 12.000 €
• Consultation with the coordinating competent authority for devices utilizing animal tissues ²	<u>Hourly</u>	250 €		250 €/h min 1.000 €- max 10.000 €
• Evaluation/review of the Periodic Safety Update Report (PSUR)	<u>Hourly</u>	250 €		250 €/h min 2.000 €- max 5.000 €
• Assessment of changes	<u>Hourly</u>	250 €		250 €/h

¹ Special conditions for manufacturers belonging to SME

² 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

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	<u>Type of Feeⁱ</u>	<u>Fee</u>	<u>Factors influencing the calculation of fee charged</u>	<u>Fee range</u>
				min 500 €- max TD re-assessment fee
Reporting (if not covered above)	<u>Flat</u> <u>Hourly</u> <u>Daily</u>	N/A	-	N/A
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	CE CERTISO Kft. applies a discounted fee for “Application fee” and “Travel time costs”			
