



LIST OF STANDARD FEES FOR CONFORMITY ASSESSMENT ACTIVITIES
UNDER THE MDR (2017/745), NOTIFIED BODY CE CERTISO KFT (NB
2409)

VALID FROM 01-01-2026

	TYPE OF FEE	FEE	FACTORS INFLUENCING THE CALCULATION OF FEE CHARGED	FEE RANGE
ADMINISTRATIVE CHARGES				
• Application fee	<u>Flat</u>	3.000 € SME ¹ : 2.250 €	--	3.000 € SME ¹ : 2.250 €
• Administrative fee related to changes	<u>Flat</u>	500 €	--	500 €
• Annual certificate maintenance fee (provide details which activities covered)	<u>Flat</u>	700 €	--	700 €/year
• Other - certificate issue fee	<u>Flat</u>	150 €	--	150 €
Travel time costs (excluding expenses such as hotel costs, travel costs)	<u>Hourly</u>	110 € SME ¹ : 80 €	• Daily allowance: 74 €/day acc. to the national legislation	220 – 3.540 € SME ¹ : 160 – 2.560 €
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>	300 €	• The number of employees • The number of sites	300 €/h <i>Audit follow-up (onsite):</i> 2.000-5.000 € + travel/accommodation cost and travel time cost, daily allowance
• Unannounced Audit	<u>Hourly</u>	300 €	--	min 10.000 € + travel/accommodation cost and travel time cost, daily allowance
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>	300 €	• The complexity of the device • Quality and structure of the TD • Review of corrections: invoiced on an hourly basis	300 €/h min 10.500 €- max 65.000 € (1 st assessment round) <i>Class I.s/m/r devices: min. 4.200 € max.15.000 €</i> (1 st assessment round)
• Clinical evaluation report assessment (CEAR)	<u>Hourly</u>	300 €	• The complexity of the device • Quality and structure of the CEP, CER • Review of corrections: invoiced on an hourly basis	300 €/h min 3.000 €- max 15.000 €
• Validation of the Summary of Safety and Clinical Performance (SSCP)	<u>Hourly</u>	300 €	• The complexity of the device • Quality and structure of the SSCP • Review of corrections: invoiced on an hourly basis	300 €/h min 2.400 €- max 9.000 €

¹ Special conditions for SMEs



LIST OF STANDARD FEES FOR CONFORMITY ASSESSMENT ACTIVITIES
UNDER THE MDR (2017/745), NOTIFIED BODY CE CERTISO KFT (NB
2409)

VALID FROM 01-01-2026

	TYPE OF FEE	FEE	FACTORS INFLUENCING THE CALCULATION OF FEE CHARGED	FEE RANGE
<ul style="list-style-type: none"> Consultation with medicinal product authorities² 	<u>Hourly</u>	300 €	<ul style="list-style-type: none"> The complexity of the device Quality and structure of the dossier Review of corrections: invoiced on an hourly basis 	300 €/h min 7.200 €- max 12.000 €
<ul style="list-style-type: none"> Consultation with human tissue and cells competent authority 	<u>N/A</u>	N/A	--	CE Certiso is not designated
<ul style="list-style-type: none"> Consultation with the coordinating competent authority for devices utilizing animal tissues² 	<u>Hourly</u>	300 €	<ul style="list-style-type: none"> The complexity of the device Quality and structure of the TD Review of corrections: invoiced on an hourly basis 	300 €/h min 6.000 €- max 18.000 €
<ul style="list-style-type: none"> Evaluation/review of the Periodic Safety Update Report (PSUR) 	<u>Hourly</u>	300 €	--	300 €/h min 3.000 €- max 9.000 €
<ul style="list-style-type: none"> Assessment of changes 	<u>Hourly</u>	300 €	<ul style="list-style-type: none"> The complexity of the change Quality and structure of the TD Review of corrections: invoiced on an hourly basis 	300 €/h min 600 € - max TD assessment fee + surveillance audit fee
Reporting (if not covered above)	<u>N/A</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"			

² Fees charged by the notified body for conducting consultations with the relevant authorities (e.g. EMA, National Competent Authorities): in addition, the fees payable to the relevant competent authority being consulted are invoiced to the customer