

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

	Type of Fee <sup>i</sup>	Fee	Factors influencing the calculation of fee charged	Fee range
<b>Administrative charges</b>				
• 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	150 €	-	150 €/h
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	150 €	-	150 €/h
<b>Auditing</b>				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	250 €	<ul style="list-style-type: none"> <li>The number of employees</li> <li>The number of sites</li> </ul>	250 €/h
• Unannounced Audit	Hourly	250 €	-	min 7.200 € + travel cost and travel time cost
<b>Product testing</b>				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	N/A	N/A	-	N/A
<b>Documentation Review</b>				
• Technical documentation assessment <sup>ii</sup>	Hourly	250 €	<ul style="list-style-type: none"> <li>The complexity of the device</li> <li>quality and structure of TD</li> </ul>	250 €/h min 5.000 €- max 60.000 €
• Clinical evaluation report assessment (CEAR)	Hourly	250 €		250 €/h min 2.500 €- max 7.500 €
• Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	250 €		250 €/h min 2.000 €- max 5.000 €
• Consultation with medicinal product authorities <sup>5</sup>	Hourly	250 €		250 €/h min 6.000 €- max 12.000 €
• Consultation with human tissue and cells competent authority <sup>5</sup>	Hourly	250 €		250 €/h min 6.000 €- max 12.000 €
• Consultation with the coordinating competent authority for devices utilizing animal tissues <sup>5</sup>	Hourly	250 €		250 €/h min 1.000 €- max 10.000 €
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	250 €		250 €/h min 2.000 €- max 5.000 €
• Assessment of changes	Hourly	250 €		250 €/h min 500 €- max TD re-assessment fee
<b>Reporting (if not covered above)</b>	Flat Hourly Daily	N/A	-	N/A