

List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745), Notified body MTIC InterCert S.r.l. (NB No 0068)

	<u>Type of Fee</u>	<u>Fee in local currency</u>	<u>Factors influencing the calculation of fee charged</u>	<u>Fee range(min-max)</u>
Administrative charges				
• Application fee	<u>Flat</u>	---	Depending on the type and complexity of medical devices	750 – 2.500
• Application fee related to changes / renewal	<u>Flat</u>	750	---	---
• Annual certificate maintenance fee (provide details which activities covered)	<u>Flat</u>	---	Depending on the type and complexity of medical devices.	800 – 3.800
• Issuing of the certificate for certification, renewal, extension, reduction of scope	<u>Flat</u>	---	Depending on the type and complexity of medical devices.	1.000 – 3.500
Travel timecosts (excluding expenses such as hotel costs)	<u>Hourly</u>	115	---	---
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	<u>Hourly</u>	230 / 262,5	Based on the Country policy (EC / Extra-EC)	---
• Unannounced Audit	<u>Hourly</u>	230 / 262,5	Based on the Country policy (EC / Extra-EC)	---
Product testing				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	<u>Flat</u>	To be assessed by internal laboratory	---	---
Documentation Review				
• Technical documentation assessment	<u>Hourly</u>	260 / 320	Based on the Country policy (EC / Extra-EC)	---
• Clinical evaluation report assessment (CEAR)	<u>Hourly</u>	260 / 320	Based on the Country policy (EC / Extra-EC)	---
• Expert panel consultation	<u>Hourly</u>	260 / 320	Based on the Country policy (EC / Extra-EC)	---
• Validation of the Summary of Safety and Clinical Performance (SSCP)	<u>Hourly</u>	260 / 320	Based on the Country policy (EC / Extra-EC)	---
• Evaluation/review of the Periodic Safety Update Report (PSUR)	<u>Hourly</u>	260 / 320	Based on the Country policy (EC / Extra-EC)	---

Medical Devices

	<u>Type of Fee</u>	<u>Fee in local currency</u>	<u>Factors influencing the calculation of fee charged</u>	<u>Fee range(min-max)</u>
<ul style="list-style-type: none">Assessment of changes	<u>Hourly</u>	260 / 320	Based on the Country policy (EC / Extra-EC)	---
Other				
Discount may be applicable, based on the countries policies.				
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	<u>Ad hoc payment terms/discount can be agreed upon in the offer.</u>			