List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745), Notified body **ICIM S.p.A.** (**NB 0425**)

	Type of Fee[i]	**Factors influencing the calculation of fee charged**[ii]	**Fee range (min)**[iii]	**Fee range (max)**[iv]
• Application fee	N. A.	-	-	-
• Daily	Daily	Daily	Daily	Daily
• Annual certificate maintenance fee (provide details which activities covered)	Included in audit fees.		-	-
• Other (specify)	N. A.	-	-	-
Travel timecosts (excluding expenses such as hotel costs)	Included in audit fees		-	-
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	For the service of carrying out tests at the ICIM laboratory, increase the amounts for individual tests by 30% to cover the costs of file management	Kind of tests.	10%	30%
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Daily	The amount may change depending on where you audit whether on nation, European or non-European territories.	€ 1.200,00	€ 1.800,00
• Unannounced Audit	Daily	The amount may change depending on where you audit whether on nation, European or non-European territories.	€ 1.200,00	€ 1.800,00
Product testing				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	For the service of carrying out tests at the ICIM laboratory, increase the amounts for individual tests by 30% to cover the costs of file management	Kind of tests.	10%	30%
Documentation Review				

	Type of Fee[i]	Factors influencing the calculation of fee charged[ii]	Fee range (min)[iii]	Fee range (max)[iv]
• Technical documentation assessment[v]	Hourly (max 8h for day)	Depends on the risk class: Class I (s,r,m) Class IIa Class IIb/IIb Imp. Class III	195,00 €/h	225,00 €/h
• Clinical evaluation report assessment (CEAR)	Hourly (max 8h for day)	Depends on the risk class: Class I (s,r,m) Class IIa Class IIb/IIb Imp. Class III	195,00 €/h	225,00 €/h
• Expert panel consultation[vi]	Daily	It depends on the number of questions asked by the clinical expert.	€ 1.500,00	€ 3.000,00
• Validation of the Summary of Safety and Clinical Performance (SSCP)	Included in clinical evaluation report assessment (CEAR)			
• Consultation with medicinal product authorities[5]	Daily	By the complexity of the question being asked and the number of competent authorities that need to be consulted	€ 1.500,00	€ 3.000,00
• Consultation with human tissue and cells competent authority[5]	NA	NA	NA	NA
• Consultation with the coordinating competent authority for devices utilizing animal tissues[5]	NA	NA	NA	NA
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Amount per unit	Depends on the risk class ranging and number of technical documentations.	€ 1.000,00	€ 5.800,00
• Assessment of changes	Amount per unit	Depends on the risk class ranging and number of technical documentations.	€ 1.500,00	€ 5.000,00
Reporting (if not covered above)	N. A.	N. A.	N. A.	N. A.

Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC [6]	For small companies, ICIM applies to a 5% discount.

[1] Please delete parts not applicable

[2] Based on the notified body's methodology for issuing quotations the relevant factors influencing the calculation should be indicate, for example the complexity of the device and the technical documentation, the

volume, quality and completeness of the technical documentation, number nonconformities raised and rounds of reviews needed. These factors should be sufficiently clear for manufacturers to be able to estimate the approximate fee.

[3] Range of expected fee to be paid: A minimum to maximum fee charged for the conformity assessment item. In special cases the fee can be different from the upper and lower limits indicated. For “flat fees” only to be filled if applicable.

[4] In case rates may differ for onsite and offsite assessments or because of any other factors, these different rates should be shown. In cases fees differ for different types of assessments these should be shown separately.

[5] If applicable, 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.
[6] Notified bodies should give an indication on their policy how SMEs are taken into consideration when setting the fee for these companies.

Ultimo caricamento del 05/12/2025