Fees for Conformity Assessment Activities (EUR)

Medical Devices Regulation (MDR) Effective 11 November 2024

The NSAI provide discounts to Small and Micro enterprises, according to Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises. The below estimated costs for all audit related activities will be reduced by 10% for Small and 20% for Micro.

Item	Type of fee	Fee	Factors influencing calculation of fee
Application fee MDR (incl. ISO 13485)	Flat	3500*	
Application fee ISO 13485 / MDSAP	Flat	2000*	
Substantial changes	Hour	685	Complexity of Change
Annual Certification Fee / year			
250 or more employees	Flat	8500	Number of FTEs
50-249 employees	Flat	5500	
11-49 employees	Flat	4000	
1-10 employees	Flat	3000	
Technical Documentation Assessments			
Technical pre-review check / Class IIa, IIb and III	Flat	5500	
Technical Documentation Assessments**	Daily	3250	Device complexity, completeness and quality of the submitted file. Min 19,500 Max 75,000
Clinical Evaluation Assessment	Daily	4050	
SSCP / PSUR	Daily	3250	
Audits			
Audit** (Certification, Recertification, Surveillance, Subcontractor/Supplier) / auditor	Daily	3000	Number of FTEs
Unannounced Audits - 1 day, two auditors	Daily	6000	
Pre and Post Audit Activities	Daily	3000	
Travel time / auditor / audit	Flat	1000	

*Includes first year annual certification fee for that program.
**Follow up on Non-Compliances are managed on an hourly rate at 685€

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