



## Fees for Conformity Assessment Activities (EUR)

Medical Devices Regulation (MDR) Effective 11 November 2024

*For MDR conformity assessments 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*	
Substantial changes	Hour	685	Complexity of Change
<b>MDR Annual Certification Fee / year</b>			
250 or more employees	Flat	8500	Number of FTEs
50-249 employees	Flat	5500	
11-49 employees	Flat	4000	
1-10 employees	Flat	3000	
<b>Technical Documentation Assessments</b>			
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	
<b>Audits</b>			
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	Half day	1000	

\*Includes first year annual certification fee for that program.

\*\*Management of Nonconformance's are invoiced in half day increments when more than 3 Nonconformance's are to be handled

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## Fees for Certification Service Activities (EUR)

ISO 13485 and MDSAP. Effective 11 November 2024

Item	Type of fee	Fee	Factors influencing calculation of fee
Application fee ISO 13485 / MDSAP	Flat	2000*	
Substantial changes	Hour	685	Complexity of Change
<b>Annual Certification Fee / year</b>			
ISO 13485 (with or without MDR)	Flat	1500	
MDSAP (above ISO 13485 annual fee)	Flat	1200	
<b>Audits</b>			
MDSAP Audit** (Certification, Recertification, Surveillance, Subcontractor/Supplier) / auditor	Daily	3000	
ISO 13485 Audit** (Certification, Recertification, Surveillance, Subcontractor/Supplier) / auditor.  This fee is for standalone ISO 13485 audits.	Daily	1900	Number of FTEs
MDSAP Pre and Post Audit Activities	Daily	3000	
ISO 13485 Pre and Post Audit Activities	Daily	1900	
MDSAP Travel time / auditor / audit	Half day	1000	
ISO 13485 Travel time / auditor / audit	Half day	650	

\*Includes first year annual certification fee for that program.

\*\*Management of Nonconformance's are invoiced in half day increments when more than 3 Nonconformance's are to be handled