



## 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	Flat	3500	
Substantial changes	Hour	685	Complexity of Change
<b>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 I	Flat	3000	Device complexity, completeness and quality of the submitted file
Technical pre-review check / Class II and III	Flat	5500	
Technical Documentation Assessments*	Daily	3250	
Clinical Evaluation	Daily	4050	
<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	Flat	1000	

\*Follow up on Non-Compliances are managed on an hourly rate at 685€

### HEAD OFFICE

**1 Swift Square.**  
Northwood, Santry,  
Dublin 9, Ireland  
T + 353 1 807 3800  
F + 353 1 807 3838  
E info@nsai.ie

[NSAI.ie](http://NSAI.ie)

### REGIONAL CENTRE

**Galway**  
Ballybrit Business Park  
H91 NX52T  
T + 353 91 771 943

### INTERNATIONAL OFFICE

**NSAI Inc.**  
20 Trafalgar Square  
Suite 603  
Nashua, NH 03063  
T +1 603 882 4412  
F +1 603 882 1985  
E info@nsaiinc.com

[NSAIinc.com](http://NSAIinc.com)