NSAI Fees for Conformity Assessment Activities (EUR)

Medical Devices Regulation (MDR and IVDR)

Updated 2021 for MDR/IVDR applications only - For External Use

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Conformity assessment Activities and their Fees

Product File Submission Inspection Check*	**€3,000**
Annual Product License*	**€2,500**

Quality System Audit Fees Per Day:

Medical Device MDR/IVDR QMS Audit **	**€2,200**

Unannounced Audit Fees Per Day:

NSAI is required to perform routine unannounced audits of manufacturers and/or their critical sub-contractors or crucial suppliers. Duration of unannounced audits is at least one day and performed by two auditors, at least once during the 5-year certification cycle with some exceptions.

Medical Device MDR/IVDR Unannounced Audit **	**€4,400**

Technical Documentation Review Fees Per Day

The review of technical documentation requires the highest levels of technical expertise. The time spent on these reviews is dependent on a number of critical factors:

- Quality and completeness of the submission
- Class of the device
- Whether the device is novel and/or high risk

Regulation (MDR/IVDR) Technical Documentation Review***	**€3,000**

Fees may vary slightly due to currencies and different travel policies that may apply to some specific geographies.

A more comprehensive breakdown of Fees is available following the RFQ/Application process.

*This fee applies to each individual product file submission

**Fees associated with travel time, expenses and other schemes are dependent on contract and geography

***This fee applies to initial conformity assessments, significant change reviews, recertification reviews, post market surveillance and vigilance activities.

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