Fees for Conformity Assessment Activities (EUR)

Medical Devices Regulation (MDR and IVDR)

Effective from 1st January 2023

Conformity Assessment Activities and their Fees

Quality Management System Audit Fees

Medical Device QMS Audit*	**€ 260 per hour**

* Exclusive of travel time and expenses

Technical Documentation Review Fees

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:

- The quality and completeness of the submission
- Type of the device
- Whether the device is novel and/or high risk
- Level of review required

Regulation (MDR/IVDR) Technical Documentation Review*	**€ 445 per hour**

* Clinical Documentation Review forms part of the Technical Documentation Review.

Unannounced Audit Fees

BSI 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 typically performed by two auditors, at least once during the 5-year certification cycle with some exceptions.

Unannounced Audit (performed by 2 auditors for 1 day)*	**€ 7,020 per day**

* Exclusive of travel time and expenses

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

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