Medical Devices

Fees for Conformity Assessment Activities (EUR)

Medical Devices Regulation (MDR and IVDR)

Effective 1 January 2021

Conformity assessment activities and their fees

Quality System Audit Fees:

Medical Device QMS Audit *(Exclusive of travel time and expenses)*	**€240 per hour**

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*	**€405 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) *(Exclusive of travel time and expenses)*	**€6,450 per day**

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

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