Fees for Conformity Assessment Activities (EUR)

Medical Devices Regulation (MDR and IVDR)

Effective 1 January 2020
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.

BSI Group EMEA
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MKS 8PP
United Kingdom
T: +44 (0)345 080 9000
E: eu.medicaldevices@bsigroup.com

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
T: +31 (0)20 346 07 80
E: eu.medicaldevices@bsigroup.com

For external use