

FEES FOR CONFORMITY ASSESSMENT ACTIVITIES MEDICAL DEVICES CERTIFICATIONS – REGULATION (EU) 2017/745 MDR

QMS (QUALITY MANAGEMENT SYSTEM) AUDIT FEES

Description	Fee per hour
QMS Audit on-site	350,00 € *

Certification audit at the organization and/or Suppliers and/or Sub-suppliers, issue of assessment reports.

* plus approximately 50% for internal activities and back-office support

- Exclusive of travel time and expenses
- Fee is intended per Auditor

PRODUCT TECHNICAL DOCUMENTATION ASSESSMENT – PRODUCT EXPERT

Description	Fee per hour
PRODUCT EXPERT ASSESSMENT	340,00 € *

Product Expert Technical Documentation Assessment

* plus approximately 50% for internal activities and back-office support

PRODUCT TECHNICAL DOCUMENTATION ASSESSMENT – CLINICAL EXPERT

Description	Fee per hour
CLINICAL EXPERT ASSESSMENT	340,00 € *

Clinical Expert Technical Documentation Assessment

* plus approximately 50% for internal activities and back-office support

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PRODUCT TECHNICAL DOCUMENTATION ASSESSMENT – CLINICAL SPECIALIST

Description	Fee per hour
Clinical Specialist Assessment	350,00 € *

Clinical Specialist Technical Documentation Assessment

* plus approximately 50% for internal activities and back-office support

UNANNOUNCED AUDIT (performed min. 1 day by 2 Auditors)

Description	Fee per hour
Unannounced Audit (performed min. 1 day by 2 Auditors)	350,00 € *

Unannounced Audit (performed min. 1 day by 2 Auditors)

* plus approximately 50% for internal activities and back-office support

- Exclusive of travel time and expenses

PSUR Periodic Assessment (Periodic Safety Update Report)

Description	Fee per hour
PSUR Periodic Assessment (Periodic Safety Assessment Report)	350,00 € *

PSUR Periodic Assessment (Periodic Safety Update Report)

* plus approximately 50% for internal activities and back-office support

Fees might suffer variations due to country specific currency, different travel policies and depending on the complexity of the project.