Table: Fees for conformity assessment according to Regulation (EU) 2017/745, Directive MDD 93/42/EEC and ISO 13485:2016

Fees	Type of Fee	Fee in EUR	Factors influencing the calculation of fee charged	Fee range (min-max)
Administrative charges				
Application fee - class Im, Is, Ir according to MDR	Flat	Min 2.500 EUR	Classification of medical device, number of medical devices…	N/A
Application fee – class IIa, IIb according to MDR	Flat	Min. 3.500 EUR	Classification of medical device, number of medical devices…	N/A
Application fee - class III according to MDR	Flat	Min. 4.500 EUR	Classification of medical device, number of medical devices…	N/A
Application fee – ISO 13485	Flat	Min. 350 EUR	Number of employees in the organization, number of locations...	
Administrative fee related to changes (MDD, MDR)	Flat	Min. 750 EUR	Identified scope of change	N/A
Administrative costs related to handling of external services (laboratories, consultation or travel expenses) (MDR)	Hourly	Min. 200 EUR/h	Depending on actual time spent	N/A
Travel time costs (excluding expenses such as hotel costs)	Hourly	Min. 50 EUR/h	Depending on hours/travel (price/travelling hour/auditor) Travelling time is considered to be the travel time from auditor's home/work to arrival at the hotel/audit location and back. When planning the audits, SIQ is committed to choose the most optimal routes, based on the availability of auditors.	N/A
Travel expenses (costs for parking, toll, flight tickets, hotel accommodation, etc.; without travel time cost)	N/A	Depending on the actual costs	Depending on the actual costs	N/A
Kilometre allowance*	N/A	0,43 EUR/km*	Expenses per km	N/A
Auditing				
Certification procedure/ QMS audit (harmonized standard EN ISO 13485)	Hourly	Min. 200 EUR/h	IAF guidelines MD9:2023: number of employees in the organization, number of locations…	N/A
Audit at subcontractors (MDD, MDR)	Flat Hourly	500 EUR Min. 250 EUR/h	Flat rate fee + hours Depending on activities performed at subcontractors, number of locations, accreditation status…	N/A
Certification procedure/QMS audit according to MDR (review of requirements, which are not included in the harmonized standard EN ISO 13485)	Hourly	Min. 200 EUR/h	Classification of medical device, number of medical devices…	N/A

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Fees	Type of Fee	Fee in EUR	Factors influencing the calculation of fee charged	Fee range (min-max)
Certification procedure fees according to MDR - class Im, Is, Ir according to MDR	Flat	Min. 1.500 EUR	Classification of medical device, number of medical devices…	N/A
Certification procedure fees according to MDR - class IIa	Flat	Min. 2.500 EUR	Classification of medical device, number of medical devices…	N/A
Certification procedure fees according to MDR - class IIb	Flat	Min. 3.000 EUR	Classification of medical device, number of medical devices…	N/A
Certification procedure fees according to MDR - class III	Flat	Min. 3.500 EUR	Classification of medical device, number of medical devices…	N/A
Annual fee class Im, Is, Ir according to MDR	Flat	Min 1.500 EUR	Classification of medical device, number of medical devices…	N/A
Annual certificate maintenance fee - class IIa according to MDR	Flat	Min 2.500 EUR	Classification of medical device, number of medical devices…	N/A
Annual certificate maintenance fee - class IIb according to MDR	Flat	Min 3.000 EUR	Classification of medical device, number of medical devices…	N/A
Annual certificate maintenance fee - class III according to MDR	Flat	Min 3.500 EUR	Classification of medical device, number of medical devices…	N/A
Unannounced audit (MDD, MDR)	Hourly/Flat	Min. 200 EUR/h + Annual certificate maintenance fee	Classification of medical device, number of medical devices…	N/A
Product testing				
Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests) (MDD, MDR)	Daily	Min. 1.100 EUR	Depending on complexity of device/testing, number of devices, no. of samples…	N/A
Documentation Review				
Technical documentation assessment (MDD, MDR)	Hourly	Min. 250 EUR/h	Classification of medical device, specific knowledge included, number of medical devices, complexity of the device, volume…	N/A
Clinical evaluation report assessment (CEAR) (including validation of the Summary of Safety and Clinical Performance (SSCP)) (MDD, MDR)	Hourly	Min. 300 EUR/h	Classification of medical device, specific knowledge included, number of medical devices, complexity of the device, volume…; indication/ intended use	N/A
Expert panel consultation (MDR)	Hourly	Min. 250 EUR/h	Classification of medical device, specific knowledge included, number of medical devices, complexity of the device, volume…; indication/ intended use	N/A

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Fees	Type of Fee	Fee in EUR	Factors influencing the calculation of fee charged	Fee range (min-max)
Consultation with medicinal product authorities (MDR)	Hourly	Min. 250 EUR/h	Classification of medical device, specific knowledge included, number of medical devices, complexity of the device, volume…; indication/ intended use	N/A
Consultation with human tissue and cells competent authority (MDR)	N/A	N/A	N/A	N/A
Consultation with the coordinating competent authority for devices utilizing animal tissues (MDR)	N/A	N/A	N/A	N/A
Evaluation/review of the Periodic Safety Update Report (PSUR) (MDD, MDR)	Hourly	Min. 250 EUR/h	Classification of medical device, specific knowledge included, number of medical devices, complexity of the device, volume…	N/A
Assessment of changes	Hourly	Min. 250 EUR/h	Identified scope of change	N/A
Issuance of certificate and decision (first issue/new issue in case of change/recertification) (MDD, MDR)	Flat	260 EUR/certificate	Number of medical devices	N/A
Issuance of certificate and decision (first issue/new issue in case of change/recertification) (ISO 13485)	Flat	250 EUR/certificate	N/A	N/A
Reporting (MDR)	Flat	Min. 480 EUR/report	N/A	N/A

*On the basis on statutory prescribed kilometre rate in Slovenia or in the country of auditor's residence

Certification procedure is described in MDR DP006 Certification according to Regulation (EU) 2017/745 on medical devices.
In determining the scope, also IAF guidelines (International Accreditation Forum) IAF MD5:2023 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems and IAF MD 9:2023 - Application of ISO/IEC 17021-1, Medical Device Quality Management Systems (ISO 13485) apply.
Certification procedure for MDD is described in MDD DP006 Certification of medical devices according to Directive 93/42/EEC.
For all procedures also AR034 Rules for management system certification apply.

For Slovene VAT-taxable legal persons, all listed prices are subject to an extra 22% VAT.