

Table: Fees according to Regulation (EU) 2017/745 on medical devices

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 1.500 EUR	Classification of medical device, number of medical devices,...	N/A
Application fee – class IIa, IIb according to MDR	Flat	Min. 2.000 EUR	Classification of medical device, number of medical devices,...	N/A
Application fee - class III according to MDR	Flat	Min. 2.500 EUR	Classification of medical device, number of medical devices,...	N/A
Administrative fee related to changes	Flat	Min. 200 EUR	Identified scope of change	N/A
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	Min. 190 EUR/h	Depending on actual time spent	N/A
Travel timecosts (excluding expenses such as hotel costs)	Flat	Min. 160-240 EUR	Depending on hours/travel	N/A
Travel expenses (costs for parking, toll, flight tickets, hotel accommodation, etc.; without travel timecost)	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. 140 EUR/h	IAF guidelines MD9:2017: number of employees in organization, number of locations,...	N/A
Audit at subcontractors	Hourly	Min. 190 EUR/h	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. 190 EUR/h	Classification of medical device, number of medical devices,...	N/A
Certification procedure fees according to MDR - class Im, Is, Ir according to MDR	Flat	Min. 750 EUR	Classification of medical device, number of medical devices,...	N/A

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Certification procedure fees according to MDR - class IIa	Flat	Min. 1.500 EUR	Classification of medical device, number of medical devices,...	N/A
Certification procedure fees according to MDR - class IIb	Flat	Min. 2.000 EUR	Classification of medical device, number of medical devices,...	N/A
Certification procedure fees according to MDR - class III	Flat	Min. 2.000 EUR	Classification of medical device, number of medical devices,...	N/A
Annual fee class Im, Is, Ir according to MDR	Flat	Min 1.250 EUR	Classification of medical device, number of medical devices,...	N/A
Annual certificate maintenance fee - class IIa according to MDR	Flat	Min 1.500 EUR	Classification of medical device, number of medical devices,...	N/A
Annual certificate maintenance fee - class IIb according to MDR	Flat	Min 2.000 EUR	Classification of medical device, number of medical devices,...	N/A
Annual certificate maintenance fee - class III according to MDR	Flat	Min 2.500 EUR	Classification of medical device, number of medical devices,...	N/A
Unannounced audit	Hourly/Flat	Min. 190 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)	Daily	Min. 1.100 EUR	Depending on complexity of device/testing, number of devices, no. of samples,...	N/A
Documentation Review				
Technical documentation assessment	Hourly	Min. 240 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))	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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Expert panel consultation	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 medicinal product authorities	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	N/A	N/A	N/A	N/A
Consultation with the coordinating competent authority for devices utilizing animal tissues	N/A	N/A	N/A	N/A
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	Min. 190 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. 190 EUR/h	Identified scope of change	N/A
Issuance of certificate and decision (first issue/new issue in case of change)	Flat	200 EUR/certificate	Number of medical devices	N/A
Reporting	Flat	360 EUR/report	N/A	N/A

*On the basis on statutory prescribed kilometre rate in Slovenia

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) MD9:2022 - Application of ISO/IEC 17021-1, Medical Device Quality Management Systems (ISO 13485)