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

Fees	Price in EUR
Basic fee – class I according to MDR	1.000 EUR
Basic fee – class Im, Is, Ir according to MDR	1.500 EUR
Basic fee –IIa, IIb according to MDR	2.000 EUR
Basic fee – class III according to MDR	2.500 EUR
Technical documentation review (per technical documentation)	Min. 240 EUR/h
Clinical evaluation review	Min. 250 EUR/h
Certification procedure/QMS audit according to MDR (review of requirements, which are not included in the harmonized standard EN ISO 13485)	Min. 190 EUR/h
Certification procedure/fees according to MDR (depending on the device class)	500 EUR – 2000 EUR
Certification procedure/ QMS audit (harmonized standard EN ISO 13485)	Min. 140 EUR/h
Annual fee class I according to MDR	1.000 EUR
Annual fee class Im, Is, Ir according to MDR	1.250 EUR
Annual fee – class IIa according to MDR	1.500 EUR
Annual fee – class IIb according to MDR	2.000 EUR
Annual fee – class III according to MDR	1.000 EUR
Annual fee for harmonized standard	2.500 EUR
Travel expenses	Depending on the actual costs
Kilometre allowance*	0,37 EUR / km
Issuance of certificate and decision (first issue/new issue in case of change)	200,00 EUR
Review of change on the product/QMS	Min. 190 EUR/h
Additional copy of A4 format certificate	50,00 EUR

*On the basis of 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) MD9:2017 - Application of ISO/IEC 17021, Medical Device Quality Management Systems (ISO 13485)