

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

<b>Fees</b>	<b>Price in EUR</b>
Basic fee – class I, Im according to MDR	500 EUR
Basic fee – class Is, Ir, IIa, IIb according to MDR	1000 EUR
Basic fee – class III according to MDR	1500 EUR
Technical documentation assessment (per technical documentation)	Min. 150 EUR/h
Clinical evaluation assessment	Min. 150 EUR/h
Certification procedure/QMS audit according to MDR (review of requirements, which are not included in the harmonized standard)	Min. 250 EUR/h
Certification procedure/QMS (harmonized standard)	Min. 150 EUR/h
Annual fee class I, Im according to MDR	350 EUR
Annual fee – class Is, Ir, IIa, IIb according to MDR	700 EUR
Annual fee – class III according to MDR	1000 EUR
Annual fee for harmonized standard	500 EUR
Travel expenses	Depending on the actual costs
Kilometer allowance*	0,37 EUR / km
Issuance of certificate and decision (first issue/new issue in case of change)	300,00 EUR
Additional copy of A4 format certificate	33,00 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) MD9:2015 - Application of ISO/IEC 17021, Medical Device Quality Management Systems (ISO 13485) and Team NB Code of Conduct for Notified Bodies are taken into consideration