

## List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745),

### Czech Metrology Institut

	Type of Fee	Fee (EUR)	Factors influencing the calculation of fee changed	Fee (min-max)
<b>Administrative charges</b>				
Application fee (including application review)	Flat	1 018	N/A	N/A
Administrative fee related to changes	Flat	1 018	Significant changes in the application	N/A
Annual certificate maintenance fee (certificate/maintenance, administration)	Flat	509	N/A	N/A
Certificate issuance fee	Flat	1 018	Additional copy of the certificate – 50 EUR	N/A
Travel time costs (excluding expenses such as hotel costs or tickets)	Hourly	51 / hour	Travel expenses are calculated according to real expenditures	N/A
Administrative costs related to handling of external services (laboratories, consultation, travel expenses)	Hourly	102 / hour	N/A	N/A
Other administrative actions	Hourly	102 / hour	N/A	N/A
<b>Auditing</b>				
Audit (Certification, Recertification)	Daily	1 425 / day	Audit days are calculated using the methodology of IAF. The fee of 1400 EUR / day is for one auditor per day. Including auditing of subcontractors or suppliers	N/A
Audit (Surveillance)	Daily	1 222 / day	Audit days are calculated using the methodology of IAF. The fee of 1200 EUR / day is for one auditor per day. Including auditing of subcontractors or suppliers	N/A
Unannounced Audit	Daily	1 120 / day	Audit days are calculated using the methodology of IAF. The fee of 1100 EUR / day is for one auditor per day	N/A
<b>Product testing</b>				
Laboratory testing in CMI laboratories (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	According to CMI official price list	Fee will be calculated according to the official price list of CMI laboratories. Otherwise, it is 240 EUR/hour	N/A
Laboratory testing in external laboratories (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	According to the price list of the laboratory	Fee will be calculated according to the official price list of the external laboratory	N/A

	Type of Fee	Fee (EUR)	Factors influencing the calculation of fee changed	Fee (min-max)
<b>Documentation Review</b>				
Technical documentation assessment for medical devices class Is, Im, Ir	Hourly	234 / hour	Includes assessment of all characteristics and aspects of technical documentation and creation of the reports. Includes max 3 rounds offsite	N/A
Technical documentation assessment for medical devices class IIa	Hourly	244 / hour	Includes assessment of all characteristics and aspects of technical documentation and creation of the reports. Includes max 3 rounds offsite	N/A
Technical documentation assessment for medical devices class IIb	Hourly	255 / hour	Includes assessment of all characteristics and aspects of technical documentation and creation of the reports. Includes max 3 rounds offsite	N/A
Technical documentation assessment for medical devices class III	/	/	/	/
Clinical evaluation report assessment (CEAR)	Hourly	305 / hour	Includes max 3 rounds offsite	N/A
Expert panel consultation	Hourly	183 / hour	N/A	N/A
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	305 / hour	N/A	N/A
Consultation with medicinal product authorities	Hourly	183 / hour	Plus fee payable to the relevant competent authority being consulted	N/A
Consultation with human tissue and cells competent authority	/	/	/	/
Consultation with the coordinating competent authority for devices utilizing animal tissues	/	/	/	/
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	244 / hour	N/A	N/A
Assessment of changes (QMS, changes referring to medical device, its design, intended purpose, manufacturer's claims, substances etc.)	Hourly	244 / hour	Significant changes – the fee is calculated according to the TF assessment fee (230/240/250 EUR/hour) Minor changes – 180 EUR/hour	180 – 250 EUR / hour
Final review and decision making on certification	Hourly	244 / hour	N/A	N/A
Literature research, data screening	Hourly	183 / hour	N/A	N/A
Reporting (if not covered above)	/	/	/	/
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	<p>When calculating the order, all the specifics are considered into account including the size of the manufacturer, number of manufacturing spots or number of employees. These aspects influence the number of audit days, which are determined using the methodology of IAF.</p> <p>Above all this, small enterprises could be granted an additional discount up to 10 % and micro enterprises up to 20 % depending on the quality of their documentation and level of readiness.</p>			