



**LIST OF STANDARD FEES
FOR CONFORMITY ASSESSMENT ACTIVITIES UNDER THE
MDR (2017/745)**

	Charge type	Fee (EUR) excluding VAT	Factors affecting the calculation of the fee charged
ADMINISTRATIVE FEES			
Application fee (including review of application)	Flat	1080	
Administrative fee related to changes	Flat	1080	Significant changes in the application.
Annual fee for maintaining the certificate (certificate/maintenance, administration)	Flat	530	
Certificate issuance fee	Flat	1050	
Fee for issuing a duplicate certificate	Flat	50	
Travel time costs (excluding travel expenses such as hotel costs or tickets)	Hourly	55 / hour	Travel expenses are calculated separately based on actual expenses.
Administrative costs related to securing external services (laboratories, consultations, travel expenses)	Hourly	110 / hour	
Other administrative measures	Hourly	110 / hour	
AUDITS			
Audit (certification, recertification, surveillance)	Daily	1495 / day	Audit days are calculated according to IAF methodology. The fee of EUR 1 495/day applies to one auditor per day. Including audits of subcontractors or suppliers.
Unannounced audit	Daily	3200 / day	Audit days are calculated according to IAF methodology. The fee of 3200/day applies to two auditors per day.

 CZECH METROLOGY INSTITUTE	Czech Metrology Institute Notified Body No. 1383 Český Metrologický Institut Oznámený subjekt č. 1383	 ČESKÝ METROLOGICKÝ INSTITUT
		Type: External document Page: 2/ 3

DEVICE TESTING			
Laboratory testing at CMI laboratories (including preparation and reporting, but excluding expenses incurred for external testing)	Hourly	According to the official CMI price list	The fee will be calculated according to the official price list of the CMI laboratories. Expenses are calculated based on actual expenses
Laboratory testing in external laboratories (including preparation and reporting)	Hourly	According to the price list of the external laboratory	The fee will be calculated according to the price list of the external laboratory. Expenses are calculated based on actual expenses
DOCUMENTATION REVIEW			
Assessment of technical documentation for medical devices of classes Is, Im, Ir	Hourly	245 / hour	Assessment of submitted technical documentation and compilation of reports. The quoted price includes a maximum of 1 round of iteration.
Assessment of technical documentation for medical devices of classes IIa	Hourly	255 / hour	Assessment of submitted technical documentation and compilation of reports. The quoted price includes a maximum of 1 round of iteration.
Assessment of technical documentation for medical devices of classes IIb	Hourly	265 / hour	Assessment of submitted technical documentation and compilation of reports. The quoted price includes a maximum of 1 round of iteration.
Assessment of technical documentation for medical devices of classes III	/	/	/
Clinical evaluation assessment including report (CEAR)	Hourly	305/ hour	The quoted price includes a maximum of 1 round of iteration.
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	305/ hour	
Consultation with an expert committee	Hourly	190 / hour	
Evaluation/review Periodic safety update reports (PSUR)	Hourly	255 / hour	
Assessment of changes (QMS, changes relating to the medical device, its design, intended purpose, manufacturer's claims, substances, etc.)	Hourly	255 / hour	Significant changes – the fee is calculated based on the TF assessment fee (EUR 245/255/265 per hour)
Final assessment and certification decision	Hourly	255 / hour	

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		Type: External document Page: 3/ 3

Literature review, data screening	Hourly	190 / hour	
Report (if not mentioned above)	/	/	/
Special conditions for producers belonging to small and medium-sized enterprises in accordance with Recommendation 2003/361/EC	All specific factors, including the size of the manufacturer, the number of production sites, and the number of employees, are taken into account when calculating the order. These aspects influence the number of audit days, which are determined using the IAF methodology.		
	In addition, small businesses could be granted an additional discount of up to 10 % and micro-businesses up to 20 %, depending on the quality of their documentation and level of preparedness.		