List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745),Notified body 0476 and 1912 (NB No)

	Type of Fee	Fee inlocal currency	Factors influencing the calculation of fee charged[2]	Fee range(min-max)[3]
Administrative charges				
• Application fee	Flat	3000		
• Notification of change/ certification changes	Flat	800		
• Extension of certification	Flat	1.500		
• Annual maintenance fee	Flat	1250		
• Certification renewel fee	Flat	3.000		
Travel time costs (excluding costs for travel and lodging)	Hourly	150	Fees may vary due to currencies, travel policies and travel to specific geographies	
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	300		
• Unannounced Audit	Daily		1 day means 1 audit plus 1 reviewer	5.600 – 8.400
• Reporting (if not covered above)	Hourly	300		
Documentation Review				
• Technical documentation assessment	Hourly	400		
• Clinical data evaluation premarket and postmarket	Hourly	400		
• Evaluation/review of the Periodic Safety Update Report(PSUR)	Hourly	400		
Other services (when applicable)				
• Expert panel consultation	Hourly	400 plus external costs related to consultations		
• Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	400		
• Reporting (if not covered above)	Hourly	400		

• Consultation with medicinal product authorities	Hourly	400 plus external costs related to consultations		
• Consultation with the coordinating competent authority for devices utilizing animal tissues	Hourly	400 plus external costs related to consultations		
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Flat	At laboratory costs +15%		
Other				
Discount may be applicable, based on the countries policies.				
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC [6]	Audit days, application and annual certificate maintenance fees are dependent on the FTE of the manufacturer.			