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

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	Type of Fee[1]	Fee in local currency	Factors influencing the calculation of fee charged[2]	Fee range(min-max)[3]
Administrative charges				
• Application fee	Flat Hourly Daily			
• Administrative fee related to changes	Flat Hourly Daily			
• Annual certificate maintenance fee (provide details which activities covered)	Flat Hourly Daily			
• Other (specify)	Flat Hourly Daily			
Travel timecosts (excluding expenses such as hotel costs)	Flat Hourly Daily			
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Flat Hourly Daily			
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Flat Hourly Daily			
• Unannounced Audit	Flat Hourly Daily			
Product testing				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Flat Hourly Daily			
Documentation Review				
• Technical documentation assessment[4]	Flat Hourly Daily			
• Clinical evaluation report assessment (CEAR)	Flat Hourly Daily			
• Expert panel consultation[5]	Flat Hourly Daily			
• Validation of the Summary of	Flat Hourly			

	Type of Fee[1]	Fee in local currency	Factors influencing the calculation of fee charged[2]	Fee range(min-max)[3]
Safety and Clinical Performance (SSCP)	Daily			
• Consultation with medicinal product authorities[5]	Flat Hourly Daily			
• Consultation with human tissue and cells competent authority[5]	Flat Hourly Daily			
• Consultation with the coordinating competent authority for devices utilizing animal tissues[5]	Flat Hourly Daily			
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Flat Hourly Daily			
• Assessment of changes	Flat Hourly Daily			
Reporting (if not covered above)	Flat Hourly Daily			
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC [6]				

Please delete parts not applicable

[2] Based on the notified body's methodology for issuing quotations the relevant factors influencing the calculation should be indicate, for example the complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, number nonconformities raised and rounds of reviews needed. These factors should be sufficiently clear for manufacturers to be able to estimate the approximate fee.

[3] Range of expected fee to be paid: A minimum to maximum fee charged for the conformity assessment item. In special cases the fee can be different from the upper and lower limits indicated. For "flat fees" only to be filled if applicable.

[4] In case rates may differ for onsite and offsite assessments or because of any other factors, these different rates should be shown. In cases fees differ for different types of assessments these should be shown separately.

[5] If applicable, fees charged by the notified body for conducting consultations with the relevant authorities (e.g. EMA, National Competent Authorities) in addition to fees payable to the relevant competent authority being consulted.

[6] Notified bodies should give an indication on their policy how SMEs are taken into consideration when setting the fee for these companies.

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