List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745)*, Notified body NB2862

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	Type of Fee	Fee in local currency SEK	Factors influencing the calculation of fee charged	Fee range(min-max)
Administrative charges				
• Application fee	N/A	None	No	N/A
• Administrative fee related to changes	Hourly	3 000	Change Notice processing: Complexity of the change.	N/A
• Annual certificate maintenance fee (provide details which activities covered)	Flat	34 800 -67 100	For new MDR certificates an additional charge of 25 000 SEK will be added to the first annual fee. Factor influencing the calculation is number of employees at time of MDR application or beginning of the year.	34 800 -67 100
• Other (specify)	N/A	N/A	N/A	N/A
Travel time costs (excluding expenses such as hotel costs)	N/A	N/A	Travel time is not charged	N/A
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	N/A	N/A	No administrative costs related to handling of external services	N/A
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Daily	41 000	Per audit day including audit planning, audit report, review of first response Corrective Action Plans, Independent Review and Certification Authority.	N/A
• Unannounced Audit	Flat	105 000	Per unannounced audit	N/A
Product testing				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Flat Hourly Daily	TBD	To be determined and communicated to client before testing	TBD

	Type of Fee	Fee in local currency SEK	Factors influencing the calculation of fee charged	Fee range(min-max)
Documentation Review				
• Technical documentation assessment	Flat	157 000	There are additions based on technologies, class and file complexity.	N/A
• Clinical evaluation report assessment (CEAR)	Hourly	5 500	TD assessment include initial clinical assessment. Clinical oversight is charge by hour	N/A
• Expert panel consultation	Flat Hourly Daily	TBD	To be determined and communicated to client before consultation	N/A
• Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	5 000	N/A	N/A
• Consultation with medicinal product authorities	Flat Hourly Daily	TBD	To be determined and communicated to client before consultation	TBD
• Consultation with human tissue and cells competent authority	Flat Hourly Daily	N/A	Not applicable out of scope	N/A
• Consultation with the coordinating competent authority for devices utilizing animal tissues	Flat Hourly Daily	N/A	Out of scope, pending scope expansion with designating authority	N/A
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	4 000	N/A	N/A
• Assessment of changes	Flat Hourly Daily	TBD	Depending on the nature of change additional audit and file assessment maybe required to be determined and communicated to client before assessment	TBD
Reporting (if not covered above)	Flat Hourly Daily	N/A	Included in above charges	N/A
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	Onsite audit duration is calculated based on the number of full-time employees.			

**** Article 50 of MDR (2017/745) & MDCG 2023-2 List of Standard fee***