List of standard fees publik

2025 year's list of Standard Fees for Conformity Assessment Activities under the MDR (2017/745), Notified body NB 3033. Accredited certification according to ISO 13485.

	Type of fee[1]	Fee in local currency SEK	Factors influencing the calculation of fee charged	Fee range SEK
Administrative charges				
Application fee MDR	N/A	N/A	N/A	N/A
MDR annual certificate fee[2]	Flat	≥ 30 000	The number of full-time employees, annual turnover, and balance sheet	30 000 – 90 000
ISO 13485 annual certificate fee	Flat	5 000	N/A	N/A
Travel costs (including travel time and travel expenses, nationally)	Flat	9 500	Number of auditors. International travel.	N/A
Administrative costs related to handling of external services (laboratories, consultation etc.)	Hourly	4 500	Completeness and quality of submission.	N/A
Auditing MDR stand alone or in combination with ISO 13485				
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)[3]	Daily	42 000	The number of full-time employees, the number of sites	N/A
Unannounced Audit, 2 auditors for 1 day, including planning and reporting	Flat	95 000	N/A	N/A
Product testing				
Laboratory testing (including preparation and reporting fee, but excluding expenditures incurred for external tests)	Hourly	4 500	Additional cost from laboratory testing organization will be charged.	TBD
Documentation Review				
Technical documentation assessment	Flat	≥155 000	Additions based on the technology, the class and the complexity of the device.	155 000 – 380 000
Clinical Evaluation Assessment Report (CEAR), above what is included in technical documentation assessment	Hourly	4 500	The technology, the class and the complexity of the device. Completeness and quality of the submitted file.	N/A
Expert panel consultation	Hourly	4 500	The technology, the class and the complexity of the device.	TBD

[1] Minimum charge, hourly rate is 1 hour.

[2] The MDR annual certificate fee takes into consideration the special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC. The MDR annual certificate fee covers costs for maintaining issued certificates, as well as safety monitoring and incident reporting, i.e. the monitoring of the product's performance in the market and the handling of reports of incidents or adverse events.

[3] The calculation of the duration of onsite audit takes into consideration the special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC. The daily audit fee is including planning and reporting, response to corrective action plan, internal and final review.

	Type of fee[1]	Fee in local currency SEK	Factors influencing the calculation of fee charged	Fee range SEK
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	4 500	The technology, the class and the complexity of the device. Completeness and quality of the submitted file.	N/A
Consultation with medicinal product authorities	Hourly	4 500	Additional cost from Authorities may occur.	TBD
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	4 500	N/A	N/A
Assessment of changes	Hourly	4 500	Complexity of the change.	N/A
Reporting Covered in above charges	N/A	N/A	Covered in above charges.	N/A