



Fees for Conformity Assessment Activities (EUR)

Fees in other currencies available upon request

Medical Devices Regulation (MDR)

Effective 1 January 2024

Administrative Charges

	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Application fee	Flat	€5,700	Maturity of QMS; Completeness and quality of submission	≥€5,700
Administration fee related to changes	Flat	€950	Completeness and quality of submission	≥€950
Annual certificate maintenance fee	Flat	€2,375	Number of FTEs	€2,375-€9,975
Certificate decision fee	Flat	€475	Conformity assessment type	€475-€715
Certificate decision fee for product-specific certificates	Flat	€4,200	Conformity assessment type	Max. €4,200
Travel time costs (excluding travel expenses such as hotel costs)	Hourly	€210	Location of manufacturer	≤€1,680/day
Administrative costs related to external services (laboratories, consultation) or other expenses	Hourly	€475	Completeness and quality of submission	≥€475

Auditing

	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Daily	€2,185	Number of FTEs; Number of sites; Factors for audit increases/reductions; Planning and reporting	€2,185/day
Unannounced audit	Daily	€4,560	Number of assessors onsite	€4,560-€8,350/day

Fees exclude travel time and expenses.

Product Testing

	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	€475 <i>BSI preparation and reporting fee (excludes laboratory testing fees)</i>	<i>Laboratory testing fees - Consult BSI for fees</i>	≥€475

Documentation Review

	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Technical documentation assessment	Daily	€3,790	Device complexity; Completeness and quality of the submitted file	≥€3,790 (4-12 days)
Clinical evaluation report assessment (CEAR)	Daily	€3,790	Device complexity; Completeness and quality of the submitted file	≥€3,790 (1-2 days)
Expert panel consultation	Hourly	€475	Device complexity; Completeness and quality of submission	≥€475
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	€475	Device complexity; Completeness and quality of submission	≥€475
Consultation with medicinal product authorities	Daily	€3,790 <i>BSI review fee (excludes external consultation fees)</i>	Completeness and quality of submission; Authority fee	≥€3,790 (2-3 days)
Consultation with human tissue and cells competent authority	Daily	€3,790 <i>BSI review fee (excludes external consultation fees)</i>	Completeness and quality of submission; Competent Authority fee	≥€3,790 (2-3 days)
Consultation with the coordinating competent authority for devices utilizing animal tissues	Daily	€3,790 <i>BSI review fee (excludes external consultation fees)</i>	Completeness and quality of submission; Competent Authority fee	≥€3,790 (2-3 days)
Evaluation/review of the Periodic Safety Update Report (PSUR)	Daily	€3,790	Device complexity; Completeness and quality of submission	≥€3,790 (1-2 days)
Assessment of changes	Hourly Daily	€475 €3,790	Type of change(s); Completeness and quality of submission	≥€475 ≥€3,790 (1 hour - 5 days)
Reporting			Covered by Technical Documentation Assessment	

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