Medical Devices

Fees for Conformity Assessment Activities (EUR)

Fees in other currencies available upon request

Medical Devices Regulation (MDR)

Effective 1 January 2023

Administrative Charges

	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Application fee	Flat	**€5,340**	Maturity of QMS; Completeness and quality of submission	≥€5,340
Administration fee related to changes	Flat	**€890**	Completeness and quality of submission	≥€890
Annual certificate maintenance fee	Flat	**€2,160**	Number of FTEs	€2,160-€6,485
Certificate decision fee	Flat	**€445**	Conformity assessment type	€445-€670
Certificate decision fee for product-specific certificates	Flat	**€4,000**	Conformity assessment type	Max. €4,000
Travel time costs (excluding travel expenses such as hotel costs)	Hourly	**€200**	Location of manufacturer	≤€1,600/day
Administrative costs related to external services (laboratories, consultation) or other expenses	Hourly	**€445**	Completeness and quality of submission	≥€445

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	**€2,080**	Number of FTEs; Number of sites; Factors for audit increases/reductions; Planning and reporting	€2,080/day
Unannounced audit	Daily	**€3,980**	Number of assessors onsite	€3,980-€7,020/day

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	**€445** *BSI preparation and reporting fee (excludes laboratory testing fees)*	*Laboratory testing fees - Consult BSI for fees*	≥€445

Documentation Review

	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Technical documentation assessment	Daily	**€3,540**	Device complexity; Completeness and quality of the submitted file	≥€3,540 (4-12 days)
Clinical evaluation report assessment (CEAR)	Daily	**€3,540**	Device complexity; Completeness and quality of the submitted file	≥€3,540 (1-2 days)
Expert panel consultation	Hourly	**€445**	Device complexity; Completeness and quality of submission	≥€445
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	**€445**	Device complexity; Completeness and quality of submission	≥€445
Consultation with medicinal product authorities	Daily	**€3,540** *BSI review fee (excludes external consultation fees)*	Completeness and quality of submission; Authority fee	≥€3,540 (2-3 days)
Consultation with human tissue and cells competent authority	Daily	**€3,540** *BSI review fee (excludes external consultation fees)*	Completeness and quality of submission; Competent Authority fee	≥€3,540 (2-3 days)
Consultation with the coordinating competent authority for devices utilizing animal tissues	Daily	**€3,540** *BSI review fee (excludes external consultation fees)*	Completeness and quality of submission; Competent Authority fee	≥€3,540 (2-3 days)
Evaluation/review of the Periodic Safety Update Report (PSUR)	Daily	**€3,540**	Device complexity; Completeness and quality of submission	≥€3,540 (1-2 days)
Assessment of changes	Hourly Daily	**€445** **€3,540**	Type of change(s); Completeness and quality of submission	≥€445 ≥€3,540 (1 hour - 5 days)
Reporting			Covered by Technical Documentation Assessment	

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