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Medical Devices

Fees for Conformity Assessment Activities (EUR)

Fees in other currencies available upon request

In Vitro Diagnostic Devices Regulation (IVDR)

Effective 1 January 2025

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Medical Devices

Administrative Charges

	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Application fee	Flat	**€5,895**	Maturity of QMS; Completeness and quality of submission	≥€5,895
Application fee – certification under Article 16(4)	Flat	**€2,948**	Maturity of QMS; Completeness and quality of submission	≥€2,948
Administration fee related to changes	Flat	**€983**	Completeness and quality of submission	≥€983
Annual certificate maintenance fee	Flat	**€2,456**	Number of FTEs	€2,456-€10,316
Annual certificate maintenance fee – certification under Article 16(4)	Flat	**€1,965**	Conformity assessment type	≥€1,965
Certificate decision fee	Flat	**€491**	Conformity assessment type	€491-€737
Certificate decision fee for product-specific certificates	Flat	**€4,355**	Conformity assessment type	Max. €4,355
Travel time costs (excluding travel expenses such as hotel costs)	Hourly	**€215**	Location of manufacturer	≤€1,720/day
Administrative costs related to external services (laboratories, consultation) or other expenses	Hourly	**€491**	Completeness and quality of submission	≥€491
Regulatory letter	Flat	**€737**	Complexity of request	≥€737

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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	**€2,245**	Number of FTEs; Number of sites; Factors for audit increases/reductions; Planning and reporting	€2,245/day
Unannounced audit	Daily	**€4,701**	Number of assessors onsite	€4,701-€8,631/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 for verification of performance (including preparation and reporting but excluding expenditures incurred for external tests)	Daily	**€491** *BSI preparation and reporting fee (excludes laboratory testing fees)*	*Laboratory testing fees - Consult BSI for fees*	≥€491
Batch testing			*Consult BSI for fees*	

Documentation Review

	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Technical documentation assessment	Daily	**€3,930**	Device complexity; Completeness and quality of the submitted file	≥€3,930 (4-12 days)
Performance Evaluation Assessment Report (PEAR)	Daily	**€3,930**	Device complexity; Completeness and quality of submission	≥€3,930 (1-2 days)
Expert panel consultation	Hourly	**€491**	Device complexity; Completeness and quality of submission	≥€491

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	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Validation of the Summary of Safety and Performance (SSP)	Hourly	**€491**	Device complexity; Completeness and quality of submission	≥€491
Consultation of a medicinal product authority for a companion diagnostic	Daily	**€3,930** *BSI review fee (excludes external consultation fees)*	Completeness and quality of submission; Authority fee	≥€3,930 (2-3 days)
Consultation of an EU reference laboratory for performance verification	Daily	**€3,930** *BSI review fee (excludes external consultation fees)*	Completeness and quality of submission; Authority fee	≥€3,930 (2-3 days)
Consultation of an EU reference laboratory for batch testing	Daily	**€3,930** *BSI review fee (excludes external consultation fees)*	Completeness and quality of submission; Authority fee	≥€3,930 (2-3 days)
Evaluation/review of the Periodic Safety Update Report (PSUR)	Daily	**€3,930**	Device complexity; Completeness and quality of submission	≥€3,930 (1-2 days)
Assessment of changes	Daily Hourly	**€3,930** **€491**	Type of change(s); Completeness and quality of submission	≥€3,930 ≥€491 (1 hour - 5 days)
Reporting			Covered by Technical Documentation Assessment	

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