Fees for Conformity Assessment Activities (EUR)

In Vitro Diagnostic Devices Regulation (IVDR)
Effective 1 January 2026

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Note: fees in other currencies are available upon request

Administrative charges

	Type of fee	Fee (EUR)	Factors influencing the calculation of fee charged	Normal range of fee (min-max)
Application fee	Flat	€6,048	Maturity of QMS; Completeness and quality of submission	≥ €6,048
Application fee – certification under Article 16(4)	Flat	€3,024	Maturity of QMS; Completeness and quality of submission	≥ €3,024
Administration fee related to changes	Flat	€1,008	Completeness and quality of submission	≥ €1,008
Annual certificate maintenance fee	Flat	€2,520	Number of FTEs	€2,520-€10,584
Annual certificate maintenance fee – certification under Article 16(4)	Flat	€2,016	Conformity assessment type	≥ €2,016
Certificate decision fee	Flat	€504	Conformity assessment type	€504 -€756
Certificate decision fee for product-specific certificates	Flat	€4,468	Conformity assessment type	Max. €4,468
Travel time costs (excluding travel expenses such as hotel costs)	Hourly	€220	Location of manufacturer	≤ €1,760/day
Administrative costs related to external services (laboratories, consultation) or other expenses	Hourly	€504	Completeness and quality of submission	≥ €504
Regulatory letter	Flat	€756	Complexity of request	≥ €756

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	€2,290	Number of FTEs; number of sites; Factors for audit increases/reductions; Planning and reporting	€2,290/day
Unannounced audit	Daily	€4,810	Number of assessors on site	€4,810-€8,842/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)	Hourly	€504*	Laboratory testing fees – consult BSI for fees	≥ €504
Batch testing			Consult BSI for fees	

*BSI preparation and reporting fee (excludes laboratory testing 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	€4,032	Device complexity; Completeness and quality of the submitted file	≥ €4,032 (4-12 days)
Performance evaluation assessment report (PEAR)	Daily	€4,032	Device complexity; Completeness and quality of submission	≥ €4,032 (1-2 days)
Expert panel consultation	Hourly	€504	Device complexity; Completeness and quality of submission	≥ €504
Validation of the Summary of Safety and Performance (SSP)	Hourly	€504	Device complexity; Completeness and quality of the submitted file	≥ €504
Consultation of a medicinal product authority for a companion diagnostic	Daily	€4,032*	Completeness and quality of submission; Authority fee	≥ €4,032 (2-3 days)
Consultation of an EU reference laboratory for performance verification	Daily	€4,032*	Completeness and quality of submission; Authority fee	≥ €4,032 (2-3 days)
Consultation of an EU reference laboratory for batch testing	Daily	€4,032*	Completeness and quality of submission; Authority fee	≥ €4,032 (2-3 days)
Evaluation/review of the Periodic Safety Update Report (PSUR)	Daily	€4,032	Device complexity; Completeness and quality of submission	≥ €4,032 (1-2 days)
Assessment of changes	Daily Hourly	€4,032 €504	Type of change(s); Completeness and quality of submission	≥ €4,032 ≥ €504 (1 hour - 5 days)
Reporting			Covered by Technical Documentation Assessment	

*BSI review fee (excludes external consultation fees)

Support for SMEs

In support of the interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC, annual management fees are structured proportionally to the number of full-time employees involved in medical device activities.

Additionally, BSI medical device Quality Management System audit durations are determined based on the guidance in IAF-MD9 [“Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)”] and IAF-MD5 [“Determination of Audit Time of Quality and Environmental management Systems”], factoring in the number of employees.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

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