Fees for Conformity Assessment Activities (EUR)

In Vitro Diagnostic Devices Regulation (IVDR)
Effective 1 January 2025

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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

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 on site	€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 for verification of performance (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	€475*	Laboratory testing fees – consult BSI for fees	≥ €475
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	€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
Validation of the Summary of Safety and Performance (SSP)	Hourly	€491	Device complexity; completeness and quality of the submitted file	≥ €491
Consultation of a medicinal product authority for a companion diagnostic	Daily	€3,930*	Completeness and quality of submission; authority fee	≥ €3,930 (2-3 days)
Consultation of an EU reference laboratory for performance verification	Daily	€3,930*	Completeness and quality of submission; authority fee	≥ €3,930 (2-3 days)
Consultation of an EU reference laboratory for batch testing	Daily	€3,930*	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	

*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.

Request a quote

Note: fees in other currencies are available upon request

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