



Fees for Conformity Assessment Activities (EUR)

Fees in other currencies available upon request

In Vitro Diagnostic Devices Regulation (IVDR)

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 for verification of performance (including preparation and reporting but excluding expenditures incurred for external tests)	Daily	€445 <i>BSI preparation and reporting fee (excludes laboratory testing fees)</i>	<i>Laboratory testing fees - Consult BSI for fees</i>	≥€445
Batch testing			<i>Consult BSI for fees</i>	

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)
Performance Evaluation Assessment Report (PEAR)	Daily	€3,540	Device complexity; Completeness and quality of submission	≥€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 Performance (SSP)	Hourly	€445	Device complexity; Completeness and quality of submission	≥€445
Consultation of a medicinal product authority for a companion diagnostic	Daily	€3,540 <i>BSI review fee (excludes external consultation fees)</i>	Completeness and quality of submission; Authority fee	≥€3,540 (2-3 days)
Consultation of an EU reference laboratory for performance verification	Daily	€3,540 <i>BSI review fee (excludes external consultation fees)</i>	Completeness and quality of submission; Authority fee	≥€3,540 (2-3 days)
Consultation of an EU reference laboratory for batch testing	Daily	€3,540 <i>BSI review fee (excludes external consultation fees)</i>	Completeness and quality of submission; 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	Daily Hourly	€3,540 €445	Type of change(s); Completeness and quality of submission	≥€3,540 ≥€445 (1 hour - 5 days)
Reporting			Covered by Technical Documentation Assessment	

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