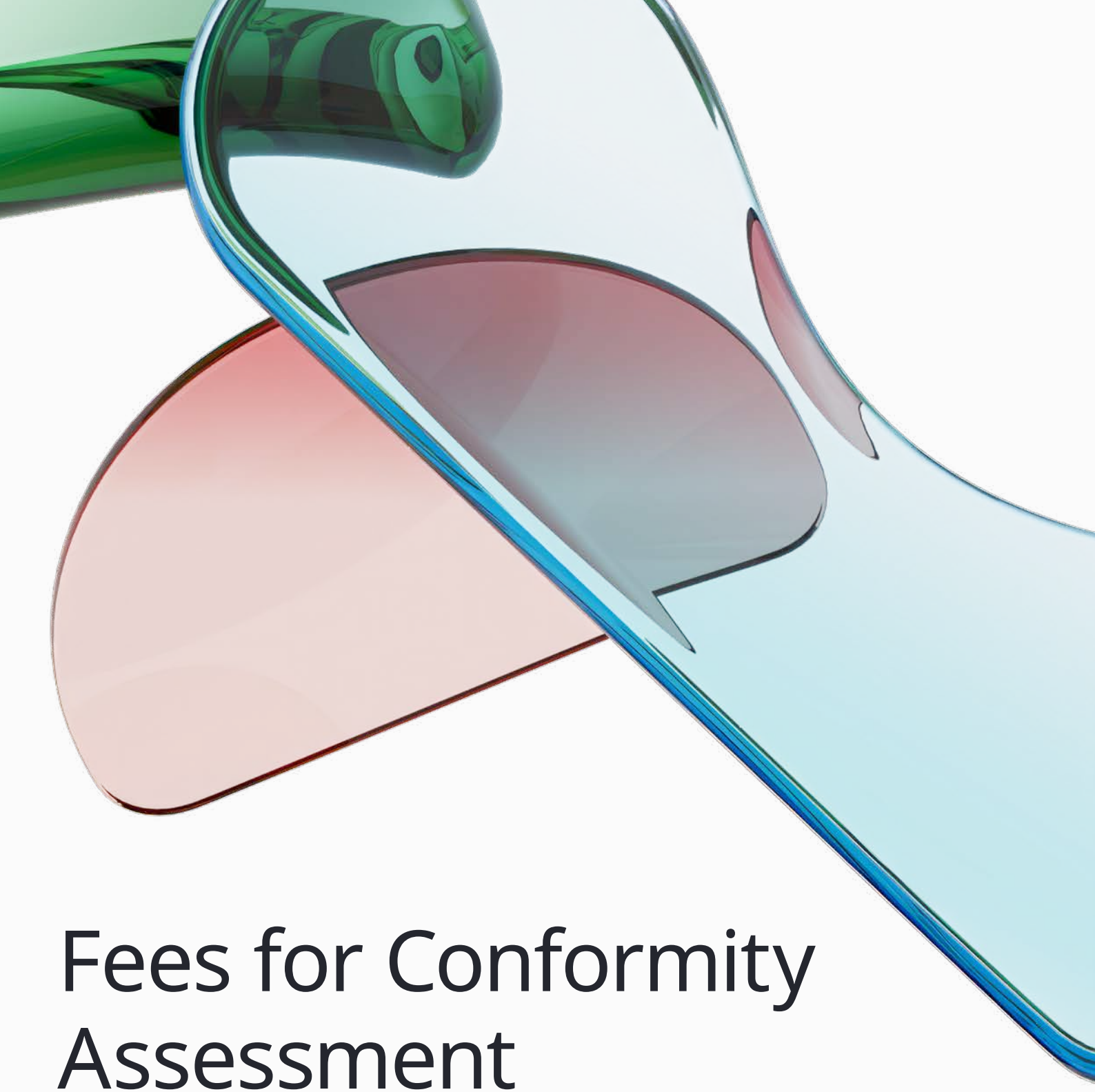

Fees for Conformity Assessment Activities (EUR)

In Vitro Diagnostic Devices Regulation (IVDR)
Effective 1 January 2024

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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	€5,700	Maturity of QMS; Completeness and quality of submission	≥ €5,700
Administration fee related to changes	Flat	€950	Completeness and quality of submission	≥ €950
Annual certificate maintenance fee	Flat	€2,375	Number of FTEs	€2,375-€9,975
Certificate decision fee	Flat	€475	Conformity assessment type	€475-€715
Certificate decision fee for product-specific certificates	Flat	€4,200	Conformity assessment type	Max. €4,200
Travel time costs (excluding travel expenses such as hotel costs)	Hourly	€210	Location of manufacturer	≤ €1,680/day
Administrative costs related to external services (laboratories, consultation) or other expenses	Hourly	€475	Completeness and quality of submission	≥ €475

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 (including preparation and reporting but excluding expenditures incurred for external tests	Daily	€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	€3,790	Device complexity; Completeness and quality of the submitted file	≥ €3,790 (4-12 days)
Performance Evaluation Assessment (PEAR)	Daily	€3,790	Device complexity; Completeness and quality of the submission	≥ €3,790 (1-2 days)
Expert panel consultation	Hourly	€475	Device complexity; Completeness and quality of submission	€475
Validation of the Summary of Safety and Performance (SSP)	Hourly	€475	Device complexity; Completeness and quality of submission	€475
Consultation of a medicinal product authority for a companion diagnostic	Daily	€3,790*	Completeness and quality of submission; Authority fee	≥ €3,790 (2-3 days)
Consultation of an EU reference laboratory for performance verification	Daily	€3,790*	Completeness and quality of submission; Authority fee	≥ €3,790 (2-3 days)
Consultation of an EU reference laboratory for batch testing	Daily	€3,790*	Completeness and quality of submission; Authority fee	≥ €3,790 (2-3 days)
Evaluation/review of the Periodic Safety Update Report (PSUR)	Daily	€3,790	Device complexity; Completeness and quality of submission	≥ €3,790 (2-3 days)
Assessment of changes	Daily Hourly	€3,790 €475	Type of change(s); Completeness and quality of submission	≥ €3,790 ≥ €475 (1 hour - 5 days)
Reporting			Covered by Technical Documentation Assessment	

*BSI review fee (excludes external consultation fees)

Note: fees in other currencies are available upon request

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