

PRICE LIST

Valid from 4.2.2025

APPLICATION FEE

Application fee is non-refundable. Receipt of payment is submitted at the same time with application. Application will not be processed prior to receipt of application fee. Application fee is dependent on the manufacturer's personnel number. Application fee and audit duration is in accordance with Commission Recommendation of 6 May 2003.

	Type of fee	Fee	Factors influencing the calculation of fee charged	Fee range (min -max)
IVDR conformity assessment according to Annex IX or Annex XI	flat	4800€	Company size	4800€-21000€

TECHNICAL DOCUMENTATION REVIEW

Review is conducted remotely by a product reviewer, internal clinician and where relevant by clinical specialist. Communication will be handled via email and file submission service. Assessment time not scheduled. Price includes 2 rounds of assessment by product reviewer, work by internal clinician, clinical specialist and final reviewer. Additional rounds of TD review cost 360€/hour.

	Type of fee	Fee	Factors influencing the calculation of fee charged	Fee range (min -max)
Technical documentation assessment according to Annex IX or Annex XI, including performance evaluation	hourly	360€	Device complexity; Risk classification, singleplex – multiplex device, intended user, sterility. Completeness and quality of the technical documentation submitted	18000-57600€

Scientific opinion from EU expert panel consultation (novel class D devices)	hourly	360€	Completeness and integrity of the technical documentation submitted	>360€, excluding direct costs from expert panel
Validation of the Summary of Safety and Performance SSP	hourly	360€	Completeness and integrity of the technical documentation submitted	>360€
Consultation with medicinal product authorities for companion diagnostic devices	hourly	360€	Completeness and integrity of the technical documentation submitted	>360€, excluding direct costs from authority
Reporting	Covered by technical documentation assessment fee			

PRODUCT TESTING

	Type of fee	Fee	Factors influencing the calculation of fee charged	Fee range (min -max)
Class D performance verification by EU reference laboratory	hourly	360€	Laboratory testing fee	2880€
Class D batch testing by EU reference laboratory	hourly	360€	Laboratory testing fee	360-1440€
For cause laboratory testing for verification of performance (including preparation	hourly	360€	Laboratory testing fee	2880€

and reporting but excluding expenditures incurred for external tests)				
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AUDIT

	Type of fee	Fee	Factors influencing the calculation of fee charged	Fee range (min -max)
Audit time on-site, off-site Initial certification; Surveillance; Recertification; Subcontractor/Supplier excluding direct travel costs (hotel, flight, daily allowance)	daily	2400€	Effective number of FTEs as per IAF MD9; Number of sites; Factors affecting audit duration	>2400€
Audit planning and reporting	flat	2400€	Effective number of FTEs as per IAF MD9; Number of sites	>2400€
Travel time	hourly	150€	location of manufacturer	>150€

ARTICLE 16 CERTIFICATE

	Type of fee	Fee	Factors influencing the calculation of fee charged	Fee range (min -max)
IVDR Article 16 certificate. Assessment activities necessary in order to certify the quality management system of a distributor or	daily	Separate pricing	Company size, maturity of QMS	>2400€

importer intended to relabel and / or repackage a device				
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SURVEILLANCE

ANNUAL FEE

Annual fee is invoiced from the beginning of the first year following the application. Annual fee is invoiced separately in January.

	Type of fee	Fee	Factors influencing the calculation of fee charged	Fee range (min -max)
IVDR conformity assessment according to Annex IX or Annex XI	flat	2400€	Company size, maturity of QMS	2400€-10500€

VALIDATION OF SUMMARY OF SAFETY AND PERFORMANCE (SSP) AND ASSESSMENT OF PERIORDIC SAFETY UPDATE REPORT (PSUR)

	Type of fee	Fee	Factors influencing the calculation of fee charged	Fee range (min -max)
Documentation Review	hourly	360€	Completeness and integrity of the technical documentation submitted	360-12880€

TECHNICAL DOCUMENTATION SAMPLING

According to IVDR and terms of conformity assessment.

Price of technical file sampling during surveillance according to routine technical file documentation price table, unless manufacturer is willing to use the scheduled route.

SURVEILLANCE AUDITS

Invoiced in ½ day increments.

	Type of fee	Fee	Factors influencing the calculation of fee charged	Fee range (min -max)
Audit time on-site, off-site Surveillance, excluding direct travel costs (hotel, flight, daily allowance)	daily	2400€	Effective number of FTEs as per IAF MD9; Number of sites; Factors affecting audit duration Planning and reporting	>2400€
Unannounced audit	daily	2400€	number of auditors	4800-9600€
Travel time	hourly	150€	location of manufacturer	>150€

VIGILANCE ACTIVITIES

	Type of fee	Fee	Factors influencing the calculation of fee charged	Fee range (min -max)
Vigilance activities. Serious incidents, field safety corrective actions, periodic safety reports and trend report	hourly	360€	Vigilance activities	>360€

SIGNIFICANT CHANGES

Assessment of significant change	hourly	360€	nature of change	>360€
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