

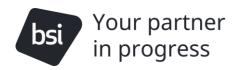


Fees for Conformity Assessment Activities (EUR)

Fees in other currencies available upon request

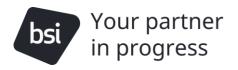
In Vitro Diagnostic Devices Regulation (IVDR)

<u>Effective 1 January 2025</u>



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 | €2,245 | Number of FTEs; Number of sites; Factors for audit increases/reductions; Planning and reporting | €2,245/day |
| Unannounced audit | Daily | €4,701 | Number of assessors onsite | €4,701- €8,631/day |

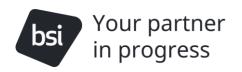
Fees exclude travel time and expenses.

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) | Daily | €491 BSI preparation and reporting fee (excludes laboratory testing fees) | Laboratory testing fees - Consult BSI for fees | ≥€491 |
| Batch testing | | | Consult BSI for 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 |



| | Type of fee | Fee (EUR) | Factors influencing the calculation of fee charged | Normal range of fee (min-max) |
|--|-----------------|--|---|---------------------------------------|
| Validation of the Summary of Safety and Performance (SSP) | Hourly | €491 | Device complexity; Completeness and quality of submission | ≥€491 |
| Consultation of a medicinal product authority for a companion diagnostic | Daily | €3,930 BSI review fee (excludes external consultation fees) | Completeness and quality of submission; Authority fee | ≥€3,930 (2-3 days) |
| Consultation of an EU reference laboratory for performance verification | Daily | €3,930 BSI review fee (excludes external consultation fees) | Completeness and quality of submission; Authority fee | ≥€3,930 (2-3 days) |
| Consultation of an EU reference laboratory for batch testing | Daily | €3,930 BSI review fee (excludes external consultation fees) | 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 | |

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