**INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.**
NOTIFIED BODY NO. 1023 UNDER REGULATION (EU) 2017/745 (MDR)

# List of NB 1023 Standard Fees

## for conformity assessment activities for medical devices under the MDR (2017/745)

| | Type of Fee | Fee in EUR | Factors influencing the calculation of fee charged | Fee range (min-max) |
|---|---|---|---|---|
| **Administrative charges** | | | | |
| • Application fee | Flat | 1580 EUR | N/A | N/A |
| • Administrative fee related to changes | Flat | 650 EUR | N/A | N/A |
| • Annual certificate maintenance fee (audit programmes, database management, maintaining NB 1023 competence) | Flat | 630 EUR | N/A | N/A |
| • Other:<br>Additional language version of the certificate<br>*Note: The price of the certification process includes a Czech and English version of the certificate.* | Flat | 20 EUR / 1 page | N/A | N/A |
| Extra copy of the certificate<br>*Note: The price of the certification process includes 1 copy of the certificate (1x Czech and 1x English version).* | Flat | 5 EUR / 1 page | N/A | N/A |
| Travel timecosts<br>*Note: Travel costs (transport, accommodation, visa, insurance, etc.) are charged separately based on actual expenses.* | Daily | 450 EUR | - | - |
| Administrative costs related to handling of external services (laboratories, consultation or travel expenses) | Hourly | 150 EUR | + fees charged by laboratory<br>+ postage costs<br>+ 0,4 EUR / 1 km | - |
| **Auditing** | | | | |
| • Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier) | Daily | 1500 EUR / 1 audit day | Audit duration (audit days) calculated as per IAF MD 9 | - |
| • Unannounced Audit | Daily | 3750 EUR | Minimum 2 auditors present 1 day on site (i.e. 2 audit days) | min 7500 EUR |

| | Type of Fee | Fee in EUR | Factors influencing the calculation of fee charged | Fee range (min-max) |
|---|---|---|---|---|
| **Product testing** | | | | |
| • Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests) | Hourly | 250 EUR | + fees charged by laboratory based on the scope of testing | - |
| **Documentation Review / Consultations** | | | | |
| • Technical documentation (TD) assessment | Hourly | 200 EUR | If the number of product models > 10, the total price for the TD assessment is increased by the coefficient k = 1.3 | min 20 000 EUR / 1 TD |
| • Clinical evaluation report assessment (CEAR) | Hourly | 250 EUR | If the number of product models > 10, the total price for the TD assessment is increased by the coefficient k = 1.3 | min 20 000 EUR / 1 TD |
| • Expert panel consultation | Hourly | 150 EUR | + fees charged by the Expert panel | min 600 EUR |
| • Validation of the Summary of Safety and Clinical Performance (SSCP) | Hourly | 150 EUR | - | min 600 EUR |
| • Consultation with medicinal product authorities | Hourly | 150 EUR | + fees charged by the medicinal authority | min 600 EUR |
| • Consultation with human tissue and cells competent authority | N/A | N/A | N/A | N/A |
| • Consultation with the coordinating competent authority for devices utilizing animal tissues | N/A | N/A | N/A | N/A |
| • Evaluation/review of the Periodic Safety Update Report (PSUR) | Hourly | 150 EUR | - | min 600 EUR |
| • Assessment of changes | Hourly | 200 EUR | 10% - 60% of the price of the initial TD assessment depending on the significance of the change | min 2000 EUR |
| **Reporting (if not covered above)** | N/A | N/A | N/A | N/A |
| Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC | 10% - 25% discount on the total price of the initial (certification) process, depending on the size of a company, number and classification of products assessed | | | |

**The above prices are indicative. A specific quotation can only be prepared after an evaluation of all necessary inputs and their impact on the scope of the conformity assessment and the resources required.**