List of Standard Fees for Conformity Assessments Activities under the IVDR (2017/746) Notified body XXXX (NB No)

|  | Type of Fee[[1]](#endnote-1) | Fee in local currency | Factors influencing the calculation of fee charged [[2]](#endnote-2)2 | Fee range (min-max) [[3]](#endnote-3)3 |
| --- | --- | --- | --- | --- |
| **Administrative charges** | | | | |
| * Application fee | Flat  Hourly  Daily |  |  |  |
| * Administrative fee related to changes | Flat  Hourly  Daily |  |  |  |
| * Annual certificate maintenance fee (please give details of activities covered) | Flat  Hourly  Daily |  |  |  |
| * Other (specify) | Flat  Hourly  Daily |  |  |  |
| Travel timecosts (excluding expenses such as hotel costs) | Flat  Hourly  Daily |  |  |  |
| Administrative costs related to handling of external services (laboratories, consultation or travel expenses) | Flat  Hourly  Daily |  |  |  |
| **Auditing** | | | | |
| * Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier) | Flat  Hourly  Daily |  |  |  |
| * Unannounced Audit | Flat  Hourly  Daily |  |  |  |
| **Product testing** | | | | |
| * Laboratory testing for verification of performance (including preparation and reporting but excluding expenditures incurred for external tests) | Flat  Hourly  Daily |  |  |  |
| * Batch testing | Flat  Hourly  Daily |  |  |  |
| **Documentation Review /Consultation** | | | | |
| * Technical documentation assessment[[4]](#endnote-4)4 | Flat  Hourly  Daily |  |  |  |
| * Performance Evaluation Assessment Report (PEAR) | Flat  Hourly  Daily |  |  |  |
| * Expert panel consultation[[5]](#footnote-1)5 | Flat  Hourly  Daily |  |  |  |
| * Validation of the Summary of Safety and Performance (SSP) | Flat  Hourly  Daily |  |  |  |
| * Consultation of a medicinal product authority for a companion diagnostic[[6]](#footnote-2) | Flat  Hourly  Daily |  |  |  |
| * Consultation of an EU reference laboratory for performance verification[[7]](#footnote-3)5 | Flat  Hourly  Daily |  |  |  |
| * Consultation of an EU reference laboratory for batch testing[[8]](#footnote-4)5 | Flat  Hourly  Daily |  |  |  |
| * Evaluation/review of the Periodic Safety Update Report (PSUR) | Flat  Hourly  Daily |  |  |  |
| * Assessment of changes | Flat  Hourly  Daily |  |  |  |
| **Reporting (if not covered above)** | Flat  Hourly  Daily |  |  |  |

|  |  |
| --- | --- |
| Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC[[9]](#endnote-5)6 |  |

1. [↑](#endnote-ref-1)
2. [↑](#endnote-ref-2)
3. [↑](#endnote-ref-3)
4. [↑](#endnote-ref-4)
5. [↑](#footnote-ref-1)
6. 1Please delete parts not applicable

   1Please delete parts not applicable

   2 Based on the notified body’s methodology for issuing quotations the relevant factors influencing the calculation should be indicated, for example the complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, number nonconformities raised and rounds of reviews needed. These factors should be sufficiently clear for manufacturers to be able to estimate the approximate fee.

   3Range of expected fee to be paid: A minimum to maximum fee charged for the conformity assessment item. In special cases the fee can be different from the upper and lower limits indicated. For “flat fees” only to be filled if applicable.

   4 In case rates may differ for onsite and offsite assessments or because of any other factors, these different rates should be shown. In cases fees differ for different types of assessments these should be shown separately.

   5 If applicable, fees charged by notified bodies for conducting consultations with the relevant authorities / expert panels / EU reference laboratories, in case notified body charges fees in addition to fees payable to the consulted bodies [↑](#footnote-ref-2)
7. 6 Notified bodies should give an indication in their policy as to how the interests of SMEs are taken into consideration when setting the fees for these companies. [↑](#footnote-ref-3)
8. [↑](#footnote-ref-4)
9. [↑](#endnote-ref-5)