I02A NR Pricelist for Conformity Assessment of Medical Devices

	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged	Fee range(min-max)
Administrative charges				
• Application fee	Flat	1000 EUR	N/A	N/A
• Administrative fee related to changes	Flat	500 EUR	N/A	N/A
• Annual certificate maintenance fee (certificate/maintenance, administration)	Flat	1000 EUR	50% discount for Surveillance Audit	N/A
• Other: Legalisation of certificate[1] - apostile	Flat	130 EUR per certificate + fees of authorities Each additional page of the certificate: 10,00 EUR / page + fees of authorities	N/A	N/A
Legalisation of certificate[1] - superlegalisation	Flat	330 EUR per certificate + fees of authorities Each additional page of the certificate: 10,00 EUR / page + fees of authorities	N/A	N/A
Extra copy of Certificate / Language mutation *Note: The price for Extra copy of Certificate includes max. 3 pages of Certificate and its Annexes.*	Flat	50 EUR / 1 certificate Each additional page of the certificate: 5 EUR / page	N/A	N/A
Formal change of certificate / Confirmation of the announced change *Note: e.g. change of name/address of client without need to perform extraordinary audit*	Flat	50 EUR / 1 certificate (+ 20 EUR for each certificate issued)	N/A	N/A
Confirmation letter as per Regulation (EU) 2023/607 (administrative costs)	Flat	150 EUR per confirmation + postage and packing	N/A	N/A
Travel timecosts (excluding expenses such as hotel costs)	Hourly	60 EUR	-	-

[1] Note: The price for Legalisation of Certificate includes max. 3 pages of the Certificate and its Annexes.
The item “Extra copy of Certificate” is charged to this item unless the client has requested legalization of copies of certificates issued to the client after certification / recertification.
If in exceptional cases the costs incurred exceed the amount set out in this price list, the price for the service will be adjusted and billed according to the actual expenses in agreement with the client.

	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged	Fee range(min-max)
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	180 EUR	Sample collection at hourly rate 180 EUR + travel costs 0,5 EUR/km + postage and packing at real cost + laboratory costs	-
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	250 EUR	Audit days calculated as per IAF MD9[2] Calculation is influenced by the factors that may increase[3] or reduce[4] duration of the audit	-
• Unannounced Audit	Flat	7200 EUR	Minimum 2 auditors for 1 day per manufacturing site	N/A
Product testing				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	N/A	N/A	N/A	N/A
Documentation Review				
• Technical documentation assessment	Hourly	300 EUR	per Technical file (with 1 intended purpose), includes 2 rounds offsite Price includes 10 variants and/or brand names. For each additional max. 10 variants and/or brand names 1 hour of	Min. 21600 EUR per Technical file (with 1 intended purpose)

[2] Fees calculated in relation to effective number of employees, number of sites, certified products, etc.

[3] Some factors that may increase the duration of the audit:

i) If more than one technical area is required to be audited, the audit time shall be extended to address any additional requirements related to the additional technical area(s); if more than one technical area will be audited, the audit time shall be extended by a minimum of 4 hours per additional technical area,

ii) the complexity of the MD / IVD MD; the audit time shall be extended by a minimum of 25%,

iii) manufacturers using subcontractors to provide processes or components that are critical to the functionality of the MD/IVD MD and/or the safety of the user or finished products including private label products. When the manufacturer cannot provide sufficient evidence of compliance with the audit criteria, an extension of audit time may be allowed for each subcontractor; audit time shall be extended by a minimum of 4 hours for each subcontractor audited for processes or components, critical suppliers beyond the time spent en route,

iv) manufacturers who install products at customer premises - time may be required to visit customer premises or review installation records; audit time shall be extended by a minimum of 10%,

v) lack of compliance with regulatory requirements by the manufacturer; audit time will be extended by a minimum of 1 audit day,

vi) multiple shifts, number of production lines, etc.; if multiple shifts will be audited, audit time will be extended by 4 hours in case of night shift, if multiple production lines producing different MD / IVD MD will be audited at the same time, audit time will be extended by a minimum of 2 hours per line.

[4] Some factors that may reduce the duration of the audit (max - 20% of the total time listed in Table 1D above):

i) Scope of the organization not including manufacturing whose activities are retail, wholesale, transport or maintenance of equipment, etc. (max - 20%),

ii) narrowing of the manufacturer's product range since the last audit (max. - 20%),

iii) narrowing of the design and/or production process since the last audit (max - 15%)

	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged	Fee range(min-max)
			technical documentation assessment fee is added. Price includes one model of MD. For each additional model 2 hours of technical documentation assessment fee is added.	
• Clinical evaluation report assessment (CEAR)	Hourly	300 EUR	per Technical file (with 1 intended purpose), includes 2 rounds offsite. Price includes 10 variants and/or brand names. For each additional max. 10 variants and/or brand names 1 hour of clinical evaluation assessment fee is added. Price includes one model of MD. For each additional model 2 hours of clinical evaluation assessment fee is added.	Min. 24000 EUR per Technical file (with 1 intended purpose)
• Expert panel consultation	Flat	1000 EUR	N/A	N/A
• Validation of the Summary of Safety and Clinical Performance (SSCP)	Flat	2500 EUR	per item	N/A
• Consultation with medicinal product authorities	Hourly	250 EUR	-	Min. 1000 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	Hourly	250 EUR	-	Min. 1000 EUR
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	250 EUR	-	Min. 1000 EUR
• Assessment of changes	Hourly	300 EUR		Min. 2400 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	30% discount from Documentation review and Auditing fees for Microenterprise 10% from Documentation review and Auditing fees for Small enterprise

Note:

Abovementioned prices are indicative. Number of submitted technical documentations, size of the company, number of locations or complexity of the project have impact on calculation of individual price offer.

The prices for the audit in Auditing section do not include travel and accommodation costs.

Prices does not include VAT.

Valid from: 01.06.2023