INSTITUTE FOR TESTING AND CERTIFICATION, a. s.

Notified Body No. 1023 under Regulation (EU) 2017/745 - MDR

Pricelist of NB 1023 services

Assessment of the technical file	
Assessment of the technical file of MD class Is, Ir, Im	230 EUR / hour
Assessment of the technical file of MD class IIa	250 EUR / hour
Assessment of the technical file of MD class IIb	265 EUR / hour
Assessment of the technical file of MD class III	280 EUR / hour
Assessment of the clinical documentation	320 EUR / hour
Consultation of a medicinal substance in MD / Clinical Evaluation Consultation Procedure (EC Expert Panel)	230 EUR / hour + fees of the competent authority / EC Expert Panel

Audit	
Initial (certification) audit	1500 EUR / day
Surveillance audit	1300 EUR / day
Participation of the clinical expert	1700 EUR / day
Participation of the technical expert	1700 EUR / day
Extraordinary audit / Follow-up audit / Unannounced audit / Audit at the subcontractor	1200 EUR / day
Note. The above audit prices include the cost of one member of the audit team for 1 day, including compensation for time spent on travel. *Travel costs (transport, accommodation, visa, insurance, etc.) are charged additionally based on actual costs.*	

Other fees of NB 1023	
Fees for certification process – registration, certificate issue, administration	1500 EUR
Note. Prices include CZ and EN version of the certificate, 1 copy up to 10 pages. For each additional page a fee of 4,- EUR / page is charged. For additional language versions a fee of 20,- EUR / 1 page is charged. The price for printing an additional copy of the certificate is 4,- EUR / 1 page.	
Annual certificate maintenance fee	500 EUR
Assessment of the non-significant change	30% of the technical documentation assessment fee
Approval of the formal change	150 EUR / hour

Assessment of the significant change	60% of the technical documentation assessment fee
Assessment of corrective actions related to findings revealed during the audit	100 EUR / nonconformity

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.