

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: Additional language version of the certificate <i>Note: The price of the certification process includes a Czech and English version of the certificate.</i>	Flat	20 EUR / 1 page	N/A	N/A
Extra copy of the certificate <i>Note: The price of the certification process includes 1 copy of the certificate (1x Czech and 1x English version).</i>	Flat	5 EUR / 1 page	N/A	N/A
Travel time-costs <i>Note: Travel costs (transport, accommodation, visa, insurance, etc.) are charged separately based on actual expenses.</i>	Daily	450 EUR	-	-
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	150 EUR	+ fees charged by laboratory + postage costs + 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
Product testing				

	Type of Fee	Fee in EUR	Factors influencing the calculation of fee charged	Fee range (min-max)
<ul style="list-style-type: none"> 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				
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> Expert panel consultation 	Hourly	150 EUR	+ fees charged by the Expert panel	min 600 EUR
<ul style="list-style-type: none"> Validation of the Summary of Safety and Clinical Performance (SSCP) 	Hourly	150 EUR	-	min 600 EUR
<ul style="list-style-type: none"> Consultation with medicinal product authorities 	Hourly	150 EUR	+ fees charged by the medicinal authority	min 600 EUR
<ul style="list-style-type: none"> Consultation with human tissue and cells competent authority 	N/A	N/A	N/A	N/A
<ul style="list-style-type: none"> Consultation with the coordinating competent authority for devices utilizing animal tissues 	N/A	N/A	N/A	N/A
<ul style="list-style-type: none"> Evaluation/review of the Periodic Safety Update Report (PSUR) 	Hourly	150 EUR	-	min 600 EUR
<ul style="list-style-type: none"> 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.