

Fees for Conformity Assessment Activities (€)

Administrative charges	Type of fee	Fee										Factors influencing the calculation of fee		Fee Range (min-max)
Application Evaluation Fee	Flat	150 €/Device										Maturity of QMS, Completeness and quality of submission		-
Administrative fee related to changes	Hourly	100 €										Completeness and quality of submission		100 €- 1600 €
Other: Transfer Audit Pre-review	Flat	2200 €										Maturity of QMS, Completeness and quality of submission		-
Other: Certificate Re-print	Flat	100€/certificate (up to 2 pages). Each additional page of the certificate: 5€/page										—		-
Annual certificate maintenance fee	Flat	EU QMS		EU QA		EU TD		ISO 13485		Importers/ Distributors				
		Cert.	Surv.	Cert.	Surv.	Cert.	Surv.	Cert.	Surv.	Cert.	Surv.	Factors influencing the calculation of fee	Fee Range (min-max)	
		6000 €	4200 €	6000 €	4200 €	7500 €	5250 €	1000 €	500 €	4500€	3150€	Conformity assessment type	-	
Travel time costs (excluding expenses such as hotel costs)	Hourly	5€/man-hour										Location of manufacturer		≥ 400 €/man-day
Administrative costs related to handling of external services (laboratories, consultation, or travel expenses)	Hourly	Laboratories: 150 € Sample collection at hourly rate 150 € + travel costs 0,5 €/km + postage and packing at real cost + laboratory costs										Completeness and quality of submission		-
	Hourly	Consultation: 150 €										Completeness and quality of submission		≥150 €
	Flat	Travel costs: Travel expenses (meal, fuel, transportation, accommodation, car park...) at real cost										Location of manufacturer		-

Auditing	Type of fee	Fee	Factors influencing the calculation of fee	Fee Range (min-max)
Site Audit & QMS Assessment (Certification, Recertification, Surveillance, Subcontractor/Supplier)	Hourly	280 €/hr	Number of sites, Factors for audit increases/ reductions, Planning and reporting	> 280 €
Unannounced/Short-notice Audit (under 2017/745)	Flat	4500 €	Number of assessors on site	-
Unannounced /Short-notice Audit (under ISO 13485)	Flat	2500 €	Number of assessors on site	-

Documentation Review	Type of fee		Fee					
		Is/Im/Ir	Ila	Ila- implant.	Ilb-non-implantable	Ilb-implantable WET	Ilb-implantable, non-WET	III
TD Assessment	Hourly	150 €/hr	180 €/hr	190 €/hr	200 €/hr	210 €/hr	220 €/hr	230 €/hr
PMS (PMS Plan, PSUR, PMCF Plan & Report) Assessment	Hourly	-	200 €/hr	210 €/hr	220 €/hr	230 €/hr	240 €/hr	250 €/hr
CER Assessment	Hourly	-	200 €/hr	210 €/hr	220 €/hr	230 €/hr	240 €/hr	250 €/hr
PMCF Assessment	Hourly	-	200 €/hr	210 €/hr	220 €/hr	230 €/hr	240 €/hr	250 €/hr
SSCP Validation	Hourly	-	-	210 €/hr	220 €/hr	230 €/hr	240 €/hr	250 €/hr
Assessment of changes	Hourly	Following the assessment of changes, the fee for the corresponding activity (such as site audit, TD assessment, etc.) will be determined.						
Expert panel consultation		To be defined by the expert panel						
Consultation with medicinal product authorities		To be defined by the medicinal product authority						

Documentation Review		Fee Range (min-max)							
		Is/lm/lr	Ila	Ila- implant.	Ilb-non-implantable	Ilb-implantable WET	Ilb-implantable, non-WET	III	
TD Assessment		> 150 €	> 180 €	>190 €	> 200 €	> 210 €	> 220 €	> 230 €	Device complexity, Completeness and quality of the submitted file
PMS (PMS Plan, PSUR, PMCF Plan & Report) Assessment		-	> 200 €	>210€	> 220 €	> 230 €	> 240 €	> 250 €	Device complexity, Completeness and quality of the submitted file
CER Assessment		-	> 200 €	>210€	> 220 €	> 230 €	> 240 €	> 250 €	Device complexity, Completeness and quality of the submitted file
SSCP Validation		-	>210€	> 220 €	> 230 €	> 240 €	> 250 €	>210€	Device complexity, Completeness and quality of the submitted file
Expert panel consultation		To be defined by the expert panel							Completeness and quality of submission, Competent Authority fee
Consultation with medicinal product authorities		To be defined by the medicinal product authority							Completeness and quality of submission, Competent Authority fee

Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC

For Medium-sized, small and micro enterprises as per the criteria below, the following discounts will be applied on the final price to be presented in the proposal.

Enterprise Category	Number of Employees*	Annual Turnover	Discount
Medium-sized	< 250	<= 50 million €	3 %
Small	< 50	<= 10 million €	5 %
Micro	< 10	<= 2 million €	7 %

Contact Information

NOTICE d.o.o.

Room 207, 208, World Trade Centre, Dunajska cesta 156, 1000
Ljubljana – Slovenia

Email: info@notice.si

Website: www.notice.si

