

## Fees for Conformity Assessment Activities (€)

Administrative charges	Type of fee	Fee						Factors influencing the calculation of fee	Fee Range (min-max)
<b>Application Evaluation Fee</b>	Flat	150 €/Device						Maturity of QMS, Completeness and quality of submission	–
<b>Administrative fee related to changes</b>	Hourly	100 €						Completeness and quality of submission	100 €- 1600 €
<b>Other: Transfer Audit Pre-review</b>	Flat	2200 €						Maturity of QMS, Completeness and quality of submission	–
<b>Other: Certificate Re-print</b>	Flat	100€/certificate (up to 2 pages). Each additional page of the certificate: 5€/page						–	–
<b>Annual certificate maintenance fee</b>	Flat	<b>EU QMS Certificate</b>		<b>EU Technical Documentation Certificate</b>		<b>ISO 13485 QMS Certificate</b>		<b>Factors influencing the calculation of fee</b>	<b>Fee Range (min-max)</b>
		<b>Certification</b>	<b>Surveillance</b>	<b>Certification</b>	<b>Surveillance</b>	<b>Certification</b>	<b>Surveillance</b>		
		6000 €	4200 €	7500 €	5250 €	1000 €	500 €	Conformity assessment type	–
<b>Travel time costs (excluding expenses such as hotel costs)</b>	Hourly	5€/man-hour						Location of manufacturer	≥ 400 €/man-day
<b>Administrative costs related to handling of external services (laboratories, consultation, or travel expenses)</b>	Hourly	<b>Laboratories:</b> 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	<b>Consultation:</b> 150 €						Completeness and quality of submission	≥150 €
	Flat	<b>Travel costs:</b> 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	220 €/hr	270 €/hr	280€/hr	290 €/hr	310 €/hr	330 €/hr	350 €/hr
PSUR Assessment	Hourly	-	310 €/hr	320€/hr	330 €/hr	350 €/hr	370 €/hr	390 €/hr
CER Assessment	Hourly	-	310 €/hr	320€/hr	330 €/hr	350 €/hr	370 €/hr	390 €/hr
PMCF Assessment	Hourly	-	310 €/hr	320€/hr	330 €/hr	350 €/hr	370 €/hr	390 €/hr
SSCP Validation	Hourly	-	-	320€/hr	-	350 €/hr	370 €/hr	390 €/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/Im/Ir	Ila	Ila- implant.	Ilb-non-implantable	Ilb-implantable WET	Ilb-implantable, non-WET	III	
<b>TD Assessment</b>	> 220 €	> 270 €	>280€	> 290 €	> 310 €	> 330 €	> 330 €	Device complexity, Completeness and quality of the submitted file
<b>PSUR Assessment</b>	-	> 310 €	>320€	> 330 €	> 350 €	> 370 €	> 390 €	Device complexity, Completeness and quality of the submitted file
<b>CER Assessment</b>	-	> 310 €	>320€	330 €	350 €	370 €	390 €	Device complexity, Completeness and quality of the submitted file
<b>PMCF Assessment</b>	-	> 310 €	>320€	> 330 €	> 350 €	> 370 €	> 390 €	Device complexity, Completeness and quality of the submitted file
<b>SSCP Validation</b>	-	-	>320€	-	> 350 €	> 370 €	> 390 €	Device complexity, Completeness and quality of the submitted file
<b>Expert panel consultation</b>		To be defined by the expert panel						Completeness and quality of submission, Competent Authority fee
<b>Consultation with medicinal product authorities</b>		To be defined by the medicinal product authority						Completeness and quality of

## 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](mailto:info@notice.si)

**Website:** [www.notice.si](http://www.notice.si)

