eurofins | Product Testing

List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745)
Notified Body Eurofins Product Testing Italy Srl (Nb. 0477)

	Type of Fee	Factors influencing the calculation of fee	Fee range (min - max)	*Cost range* (min - max)*
Administrative / Annual Fees and other cost				
Application Fee	Flat	Nb. of FTE	FTE <50: 1.500 € 50<FTE<250: 2.500 € FTE>250: 3.500 €	*1.500€ / 3.500€*
Annual certificate maintenance fee - Certification and Recertification	Flat	Nb. of FTE	FTE <50: 1.000 € 50<FTE<250: 1.500 € FTE>250: 2.000 €	*1.000€ / 2.000€*
Annual certificate maintenance fee -Yearly Surveillances	Flat	Nb. of FTE	FTE <50: 750 € 50<FTE<250: 1.000 € FTE>250: 1.250 €	*750€ / 1.250€*
Certificate issue	Flat	N/A	500 €	*500€*
Certificate revision	Flat	N/A	350 €	*350€*
Auditing				
Audit (Certification, Re-certification, Surveillance)	Daily	N. of FTE, N. and type of devices	2.000 €	*2.000€-40.000€ / per site*
Unannounced Audit	Daily	N. of devices, device type, type of process	2.000 €	*4.000€-10.000€*
Travel time	Hourly	Travel duration	137,5 €	
Travel costs	At cost	Travel expenses	at cost +10%	
Documentation Review				
Application Review	Hourly	Device classification, Doc. Complexity & quality	250 €	*750€ / 3.000€*
Technical documentation assessment	Hourly	Device classification, Doc. Complexity & quality	250 €	*7.000€ / 35.000€ (+ resubmissions)*
Changes assessment	Hourly	Type of change, Doc. Complexity & quality	250 €	*750€ / 35.000€ (+ resubmissions)*
Clinical evaluation report assessment (CEAR)	Hourly	Device classification, Doc. Complexity & quality	250 €	*6.000€ / 15.000€ (+ resubmissions)*
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	Device classification, Doc. Complexity & quality	250 €	*2.000€ / 6.000€*
Validation of the Summary of Safety and Performance (SSP)	Hourly	Device classification, Doc. Complexity & quality	250 €	*2.000€ / 6.000€*
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	Doc. Complexity & quality	250 €	*2.000€ / 6.000€*
Consultation with medicinal product authorities	Hourly	Doc. Complexity & quality	250 €	*2.000€ / 20.000€ (+ resubmissions)*
Consultation with the coordinating competent authority for devices utilizing animal tissues	Hourly	Doc. Complexity & quality	250 €	*2.000€ / 20.000€ (+ resubmissions)*
Consultations with the expert panels	Hourly	Doc. Complexity & quality	250 €	*4.000€ / 20.000€ (+ resubmissions)*
Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	Doc. Complexity & quality	250 €	*2.000€ / 20.000€ (+ resubmissions)*
Agencies/Authorities Cost (EMA, National Competent Authorities,..)	At cost	Agencies / Authorities Cost	At Cost	
Reporting				
Reporting			Included above	

Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	*Audit days, Application Fee and Annual Fees are dependent on the size (FTE) of the manufacturer*

** Min and Max Cost range is a reasonable estimation based on the experiences made so far with the management of the commitments necessary to carry out the certification processes. Actual commitments and consequent maximum values may be increased because of many factors not predictable (Eg. complexity and quality of the technical documentation, number and variants of device, number and types of findings, number of doc. re-verification needed)*

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