SZUTEST
Konformitätsbewertungsstelle GmbH

List of Standard Fees According to Regulation (EU) 2017/745

A) APPLICATION FEES

Product Risk Class	Fees	Type	Remarks
Class Is, Im, Ir and Sterile Systems or Procedure Packs	1000 Euro	FLAT	If more than one device is involved, the fee for highest product risk class is applied.
Class IIa	1500 Euro		
Class IIb non-implantable	2000 Euro		
Class IIb implant	2500 Euro		
Class IIb active devices intended to administer and/or remove a medicinal product	3000 Euro		
Class III	3500 Euro		
Class III implantable	4000 Euro		

B) ANNUAL CERTIFICATE USAGE FEE

Product Risk Class	Fees	Type	Remarks
Class Is, Im, Ir and Sterile Systems or Procedure Packs	5000 Euro	FLAT	If more than one device is involved, the fee for highest product risk class is applied.
Class IIa	7000 Euro		
Class IIb non-implantable	9000 Euro		
Class IIb implantable	11000 Euro		
Class IIb active devices intended to administer and/or remove a medicinal product	13000 Euro		
Class III	15000 Euro		
Class III implantable	17000 Euro		

C) AUDIT MAN/DAY FEE

Location	Fees	Type	Remarks
EU Countries	2500 Euro	DAILY (MAN/DAY)	Calculated mainly based on IAF MD-9 by applying several increasing and decreasing factors.
Others	2500 Euro		

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D) TECHNICAL DOCUMENTATION REVIEW MAN/DAY FEE

Location	Fees	Type	Remarks
EU Countries	2500 Euro	DAILY (MAN/DAY)	Time spent will be calculated based on the product risk class. Following factors will increase the duration per device, - PSUR, PMCF, SSCP, PMS Reviews -Routine reviews on Technical Documentation changes - Devices in sterile condition and number of applied sterilization methods - Devices requiring biocompatibility review - Devices incorporating software - Devices that are absorbable or locally dispersed - Pre-market clinical investigation review - Medicinal Product Authority Consultation - Clinical Evaluation Consultation Procedure - Consultation procedure for devices that are systemically absorbed
Others	2500 Euro		

E) ADMINISTRATIVE AND OTHER FEES

Task		Fees	Type	Remarks
Initial review on changes	Class Is, Im, Ir and Sterile Systems or Procedure Packs	100 Euro	FLAT	If more than one device is involved in certification scope, the fee for highest product risk class is applied.
	Class IIa	150 Euro	FLAT	
	Class IIb non-implantable	200 Euro	FLAT	
	Class IIb implantable	250 Euro	FLAT	
	Class IIb active devices intended to administer and/or remove a medicinal product	250 Euro	FLAT	
	Class III	300 Euro	FLAT	
	Class III implantable	350 Euro	FLAT	
Administrative task for outgoing transfers		500 Euro	FLAT	Fees to be paid to the authorities are to be invoiced separately based on the rates available during the consultation process.
Preparation and follow-up activities for authority consultations		100 Euro	HOURLY	
Assessment on appeals		100 Euro	HOURLY	
Travel Time (excluding travel and accommodation expenses)		50 Euro	HOURLY	

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F) FEES FOR REPEATING NON-CONFORMITY CORRECTIONS

Task	Fees	Type	Remarks
Repeating Non-conformity Correction	350 Euro	FLAT (Per each repeating non-conformity review)	The contract will include one-time review of the non-conformities. For repeating non-conformity reviews within defined deadline will be invoiced separately. Repeating reviews will not be conducted once the deadlines are reached.

G) FEE CALCULATION PARAMETERS

Type of Assessment	Application Fee	Annual Certificate Usage Fee	Audit Fee	Technical Documentation Review Fee
Initial Assessment	+	+	+	+
Surveillance Assessment	-	+	+	+
Re-Assessment	+	+	+	+
Transfer Assessment (From another Notified Body to SZUTEST)	+	+	+	o
Transfer Assessment (From SZUTEST to another Notified Body)	***	-	-	-
Change Assessment	**	-	o	o
Scope Extension Assessment	+	*	o	o
Unannounced Site Audit	-	-	+	-
Follow Up Audit	-	-	+	-

***'o':** Optional* ***'+':** to be calculated* ***'-':** not to be calculated.*

* *For higher product classes*

** *The application fees to be invoiced for change assessment are given in section E.*

*** *The expenses to be invoiced for administrative work in case of a transfer from SZUTEST to another notified body is 500 EUR.*

H) SPECIAL CONDITIONS FOR MANUFACTURERS BELONGING TO SMEs AS DEFINED IN RECOMMENDATION 2003/361/EC

%3 of discount is applied for SMEs from the total initial and re-certification contract amount.