

ADMINISTRATIVE CHARGES				
	<i>Type of Fee</i>	<i>Fee *</i>	<i>Factors influencing the calculation of fee charged</i>	<i>Fee range (min-max)</i>
Application/surveillance information review fees	Flat	500 €	The fee determined varies depending on the risk, quantity of the product etc. within the scope of the application.	≥ 2.500 €
Annual certification usage fee	Flat	2.000 €	The fee determined according to the risk classes and the number of products varies.	2.000 € - 10.500 €
Administrative fees (Certificate printing fees)	Flat	Certificate re-issue (minor changes): 200 € Copies of certificates: 100 € Additional copies above 10 (each): 10 €	It differs according to the number of certificates.	≥ 10 €
Borderline products opinion fee	Flat	Per each borderline product: 500 €	It differs according to the number of borderline products.	≥ 500 €
Administrative fee for transferring the certificate from UDEM A.Ş. to another notified body	Flat	2.000 €	It differs according to the number of certificates.	≥ 2.000 €
Administrative fee within the scope of short-notice and follow-up audits	Flat	1.000 €	-	1.000 €
Travel time costs (excluding expenses such as hotel costs)	Hourly Daily	Travel Time: 100 € / hour Daily Allowance: 100 €	It differs according to travel time.	≥ 100 €
SITE AUDITS				
	<i>Type of Fee</i>	<i>Fee*</i>	<i>Factors influencing the calculation of fee charged</i>	<i>Fee range (min-max)</i>
Audit (Certification, Surveillance, Recertification, Subcontractor/Supplier, Follow-up etc.)	Daily	Man / day fee: 2.500 €	Audit time differs according to the complexity of production, multiple production sites, integrated audit, etc.	≥ 2.000 €

Unannounced Audit	Daily	Unannounced Audit Fee (including preparation, one day audit with two auditors and reporting): 5.000 €	It is calculated separately for each site inspected, including the sites of the manufacturer's suppliers/subcontractors.	≥ 5.000 €
DOCUMENTATION REVIEW				
	<i>Type of Fee</i>	<i>Fee*</i>	<i>Factors influencing the calculation of fee charged</i>	<i>Fee range (min-max)</i>
Technical documentation assessment (PSUR inc.)	Daily	Man / day fee: 3.000 €	Audit time differs according to the complexity and risk class of the device.	≥ 3.000 €
Clinical data assessment including clinical evaluation report assessment (PSUR inc.)	Daily	Man / day fee: 4.500 €	The audit time differs according to the complexity, newness and risk class of the device.	≥ 4.500 €
Microbiological Evaluation	Daily	Man / day fee: 2.500 €	If more than one sterilisation method is used, the audit time differs.	≥ 2.500 €
Evaluation of product incorporating medicinal substance and/or absorbable substances	Daily	Man / day fee: 5.000 €	The audit time differs according to the complexity, newness and risk class of the device.	≥ 5.000 €
Software Validation Evaluation	Daily	Man / day fee: 4.000 €	The audit time differs according to the complexity, newness and risk class of the software.	≥ 4.000 €
IVD Evaluation	Daily	Man / day fee: 2.500 €	The audit time differs according to the complexity, newness and risk class of the device.	≥ 2.500 €
Machine Directive Evaluation	Daily	Man / day fee: 2.500 €	The audit time differs according to the complexity, newness and risk class of the device.	≥ 2.500 €
PMCF / SSCP Evaluation	Daily	Man / day fee: 4.000 €	It differs according to the number of audit days.	≥ 4.000 €
Assessment of changes	Daily	Man/day fee: depends on review type (i.e., man/day fee for technical documentation is applied for the	-	-

		changes need an assessment of technical documentation)		
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC		Taken into account 2017/745/EU MDR Annex VII Cl. 1.2.8 and 2003/361/EC Commission Recommendation; for Annual Certification Fee the following discounts are applied to the SMEs (Small Medium Enterprises): <ul style="list-style-type: none">• %15 discount for Micro Enterprises• %10 discount for Small Enterprises• %5 discount for Medium-Sized Enterprises		

Additional Remarks for Fees Charged by UDEM A.Ş.:

- Additional expenses such as travel and accommodation are not included in the site audit fees and these costs are paid by the manufacturer after the audit.
- Test and all related external costs about the testing of the product are paid by the customer.
- All external costs for the consultation process with the competent authority and/or EMA scientific opinion and/or expert panel are paid by the customer.
- Fees of all audits and assessments are based on man / day fee. Observers, candidate auditors are not included to audit duration.
- All of abovementioned fees don't include VAT.
- This list has been created taken into account the standard fees and related financial conditions defined in MDRTL.M.05 Medical Device Charging Instruction, using the template table in the MDCG 2023-2 Guidance Document on List of Standard Fees.
- This list is updated accordingly whenever MDRTL.M.05 Medical Device Charging Instruction is revised by UDEM A.Ş.
- The application review fee is not refundable under any circumstances after the contract is signed.

** Payments of domestic companies are collected in Turkish Lira at the exchange rate on the date of payment.*