

ADMINISTRATIVE CHARGES				
Activity	Type of Fee	Fee *	Factors influencing the calculation of fee charged	Fee range (min-max)
Application/surveillance information review fees	Proportional Price	10% of the contract price	The fee determined varies depending on the risk, quantity of the product etc. within the scope of the application.	The price is calculated based on the contract price.
Annual Certificate usage fee	Base Price	2.000 €	The fee determined according to the risk classes and the number of products varies.	2.000 € - 10.500 €
Certificate Printing Fees (Certificate addition and revision)	Base Price	Certificate re-issue (minor changes): 500 € Copies of certificates: 100 € Additional copies above 10 (each): 20 €	It differs according to the number of certificates.	≥ 20 €
Borderline products opinion fee	Base Price	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	Base Price	2.000 €	It differs according to the number of certificates.	≥ 2.000 €
Administrative fee within the scope of follow-up audits	Flat	1.000 €	-	1.000 €
Administrative Fee for Short-Term Audits (Vigilance, complaints, etc.)	Flat	1.000 €	-	1.000 €
Administrative Fee for Additional Supplier Audits	Flat	1.000 €	-	1.000 €
Travel costs (excluding expenses such as hotel costs)	Hourly Daily	Travel Time: 100 € / hour Daily Allowance: 100 €	It differs according to travel time.	≥ 100 €
Evaluation of Changes Administrative Fee	Flat	1.000 €	-	1.000 €

Expert Panel Consultation Process Review Fee	Per File	2500 €	It differs depending on the number of files.	≥ 2500 €
Medicinal Product Consultation Process Review Fee	Per File	2500 €	It differs depending on the number of files.	≥ 2500 €
Absorbable Product Consultation Process Review Fee	Per File	2500 €	It differs depending on the number of files.	≥ 2500 €
SITE AUDITS				
Activity	Type of Fee	Fee*	Factors influencing the calculation of fee charged	Fee range (min-max)
QMS 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				
Activity	Type of Fee	Fee*	Factors influencing the calculation of fee charged	Fee range (min-max)
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 assesment of clinical evaluation and 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 €
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
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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 MDRTLM.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 MDRTLM.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.



MDR LIST OF STANDARD FEES

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