

List of Standard Fees for Conformity Assessment Activities

under the MDR (2017/745)

UDEM ADRIATIC D.O.O. (NB 2696)



	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged
Administrative Charges			
<ul style="list-style-type: none"> Annual certificate usage fee 	Flat	For Class I device: 1000 € For Class IIa device: 1500 € For Class IIb device: 2000 € Implantable IIb /Active (Rule 12) IIb Devices: 2500 € For Class III device: 3000 €	For the SMEs (Small Medium Enterprises) following discounts are applied: <ul style="list-style-type: none"> %30 discount for Micro Enterprises %20 discount for Small Enterprises %10 discount for Medium-Sized Enterprises
<ul style="list-style-type: none"> Renewal of certificates fee 	Flat	5 year Renewal Fee EU Quality Management System Certificate: 3000 € 4 year Renewal Fee EU Quality Management System Certificate: 2500 € 3 year Renewal Fee EU Quality Management System Certificate: 2000 € 5 year Renewal Fee EU Quality Assurance Certificate: 4000 € 4 year Renewal Fee EU Quality Assurance Certificate: 3500 € 3 year Renewal Fee EU Quality Assurance Certificate: 3000 € 4 year Renewal Fee EU Technical Documentation Assessment Certificate: 5000 € 3 year Renewal Fee EU Technical Documentation Assessment Certificate: 4000 €	
<ul style="list-style-type: none"> Administration fees (Certificate printing fees) 	Flat	Certificate re-issue (minor changes): 300 € Copies of certificates: 100 € Additional copies above 10 (each): 10 €	

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<ul style="list-style-type: none"> Travel timecosts (excluding expenses such as hotel costs) 	Hourly Daily	Travel Time: 100 € / hour Daily Allowance: 100 €	
Auditing			
<ul style="list-style-type: none"> Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier) 	Daily	Man / day fee: 2.000 €	For integrated audit (System Certification and Product Certification), discount can be realized. This discount cannot exceed 20%.
<ul style="list-style-type: none"> Unannounced Audit 	Daily	Unannounced Audit Fee (including preparation, one day audit with two auditors and reporting): 6.200 € / per day	<p>The unannounced audit fee is calculated separately for each site audited, including the sites of the manufacturer's suppliers /subcontractors.</p> <p>Additional expenses such as travel and accommodation are not included in the unannounced audit fee and these costs are paid by the manufacturer after the audit.</p>
Documentation Review			
<ul style="list-style-type: none"> Technical documentation assessment 	Daily	Man / day fee: 3.200 €	
<ul style="list-style-type: none"> Clinical data assessment including clinical evaluation report assessment (CEAR) 	Daily	Man / day fee: 5000 €	
<ul style="list-style-type: none"> Microbiological Evaluation 	Daily	Man / day fee: 2000 €	
<ul style="list-style-type: none"> Evaluation of product incorporating medicinal substance and/or absorbable substances 	Daily	Man / day fee: 10.000 €	

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• Software Validation Evaluation	Daily	Man / day fee: 3.200 €	
• Assessment of changes	Daily	Man/day fee: 2.400 €	
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">• %30 discount for Micro Enterprises• %20 discount for Small Enterprises• %10 discount for Medium-Sized Enterprises		

Additional Remarks for Fees Charged by UDEM Adriatic d.o.o.:

- The application review fee is calculated for customers as 10% of the initial certification fee specified in the Medical Devices Product Certification Contract.
- Validation of the Summary of Safety and Clinical Performance (SSCP) Fees:
For initial certification, the fees for the SSCP review are calculated on the basis man / day fee according to assessment fees of technical documentation and clinical evaluation.
For surveillance assessments, the fees for the SSCP review are calculated as half of the man/day fee that defined for the assessment of technical documentation and clinical evaluation.
- Evaluation/review of the Periodic Safety Update Report (PSUR) Fees:
For initial certification; the fees for the PSUR review are calculated on the basis man / day fee according to assessment fees of technical documentation and clinical evaluation.
For surveillance assessments; the fees for the PSUR review are calculated as half of the man/day fee that defined for the assessment of technical documentation and clinical evaluation.
- Test and all related external costs about the testing of the product are paid by the customer.
- All external costs for expert panel consultation are paid by the customer.
- All external costs for consultation with medicinal product authorities / EMA are paid by the customer.
- Fees of all audits and technical/clinical assessments including PSUR and SSCP reviews are based on man / day fee. Observers, candidate auditors are not included to man / day number.
- 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 the UDTLM.17-1 Medical Devices Regulation Conformity Assessment Charging Instruction, using the template table in the MDCG 2023-2 Guidance Document on List of Standard Fees.
- This list is updated accordingly whenever UDTLM.17-1 Medical Devices Regulation Conformity Assessment Charging Instruction is revised by UDEM Adriatic d.o.o.