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 the fee charged
Administrative Charges			
• 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 and Medium Enterprises), the following discounts are applied: • %30 discount for Micro Enterprises • %20 discount for Small Enterprises • %10 discount for Medium-Sized Enterprises
• Renewal of certificates fee	Flat		Certificates are renewed upon expiration, provided that all applicable renewal requirements are met. Annual usage fees apply to these renewals.
• Administration fees (Certificate printing fees)	Flat	Certificate re-issue (minor changes): 300 € Copies of certificates: 100 € Additional copies above 10 (each): 10 €	
• Travel time costs (excluding expenses such as hotel costs)	Hourly Daily	Travel Time: 100 € / hour Daily Allowance: 100 €	
Auditing			
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Daily	Man/day fee: 2.000 €	For integrated audit (System Certification and Product Certification), a discount can be realized. This discount cannot exceed 20%.
• Unannounced Audit	Daily	Unannounced Audit Fee (including preparation, one day audit with two	The unannounced audit fee is calculated separately for each site audited, including

	Type of Fee	**Fee in local currency**	**Factors influencing the calculation of the fee charged**
		auditors and reporting): 6.200 € / per day	the sites of the manufacturer's suppliers /subcontractors. 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.
Documentation Review			
• Technical documentation assessment	Daily	Man/day fee: 3.200 €	
• Clinical data assessment including clinical evaluation report assessment (CEAR)	Daily	Man/day fee: 5000 €	
• Microbiological Evaluation	Daily	Man/day fee: 2000 €	
• Evaluation of product incorporating medicinal substance and/or absorbable substances	Daily	Man/day fee: 10.000 €	
• 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	Taking into account 2017/745/EU MDR Annex VII Cl. 1.2.8 and 2003/361/EC Commission Recommendation; for the Annual Certification Fee, the following discounts are applied to SMEs (Small and Medium Enterprises): • %30 discount for Micro Enterprises • %20 discount for Small Enterprises • %10 discount for Medium-Sized Enterprises

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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 Regulation 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 is 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 the 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 is 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 and candidate auditors are not included to man/day number.
- All of the above-mentioned fees don't include VAT.
- This list has been created taking 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.