ACILA AG

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CERTIFICATE of CONFORMITY

Date of conformity:	2026-07-08
Product:	**STERICERT®** **Sample bottle** **double bagged in SteriBags**
Volume:	1.000 ml
Product no.:	1960442/1960442-006
Lot no.:	30143
Expiry date:	2030-05-31

E: We herby certify, that the above mentioned Product meets the requirements of EP and USP and our specifications. It is suitable as primary container for pharmaceutical use.

Description	clear glass infusion bottle hydrolytic class II, with a 32 mm injection flange. They are sealed with a septum and a flange tear-off cap. On the inside, the vials are sterile and moistened with 5mL of ACILA® LRW.	
Material		
Sample bottlel	Bottle for infusion glass type II (ISO8536-1-A) in accordance with EP 3.2.1 und / and USP <661>	
Stopper	Brombutyl rubber stopper for multiple piercing type I in accordance with EP 3.2.9 and USP <381> and DIN 8362 part 2	
Cap	Flip cap in accordance with DIN ISO 8362.3	
Water for injection	in accordance with EP und / and USP	
Plastic Bag	Paper and film sterilisation pouches (SteriBags)	
Treatment and testing		
1. Sample bottle		
Sterilization Method	Steam sterilisation in accordance with EP 5.1.1 and USP <1211>	
Sterility test	in accordance with EP 2.6.1 and USP <71> Specification: sterile	Result: meets
Endotoxintest Method	kinetic turbidimetric LAL-test - Ph. Eur.2.6.14, Method C ; - USP <85> - ANSI/AAMI ST72:2019 - USP <1225> ; USP <1226> (Verification of Compendial Procedures	
	Specification	Result
	< 0,001 I.E. / mL / < 0.001 IU / mL <0,2 I.E./ vial / <0,2 I.E. / vial	Meets Meets
Particle		
Test method	Light scattering in accordance with EP 2.9.19	
	Spezification < 0,3 / mL (particles ≥ 25µm) < 2,5 / mL (particles ≥ 10µm)	 meets meets
2. Sample bottle double wrapped in steriBags		
Sterilization Method Provider Run (Lot):	Ethylene oxide in accordance with EN ISO 11135:2020 MEDICOPLAST International GmbH 19472	
Sterility test	in accordance ISO 11138-2 and EP 5.1.1 Specification: sterile	Result: meets

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Vorstand: Mustafa Mentes
Amtsgericht Darmstadt: HRB 54830
USt-IdNr.: DE111632765

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