

Opelstr. 14
D-64546 Mörfelden-Walldorf
Telefon: +49-(0)6105-9301-0
Telefax: +49-(0)6105-9301-15
E-Mail: info@acila.com
Internet: www.acila.com

CERTIFICATE of CONFORMITY

Datum der Konformität / date of conformity:	2025-12-30
Produkt / product:	STERICERT® Sample bottle bagged in SteriBags
Volumen / volume:	100 ml
Artikelnr. / product no.:	1960305-012
Ch.-B. / lot no.:	29822.1
Retest:	2030-05-31

E: We hereby 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 1, with a injection flange. They are sealed with a septum and a flange tear-off cap. On the inside, the vials are sterile and moistened with 1mL of ACILA® LRW.	
Material		
Sample bottle	Bottle for infusion glass type I in accordance with EP 3.2.1 and USP <661>	
Stopper	Chlorobutyl 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 part 3	
Water for injection	In accordance with EP and USP	
Plastic Bag	Paper and film sterilisation pouches (SteriBags)	
Treatment and testing		
1. Sample bottle		
Serilization		
Method	Steam sterilisation in accordance with EP 5.1.1 and USP <1211>	
Sterility test	in accordance with EP 2.6.1 und / and USP <71>	Result: meets
Endotoxin test		
Test method	kinetic turbidimetric LAL-test - Ph. Eur.2.6.14, Method C - USP <85> - ANSI/AAMI ST72:2019 - USP <1225> and <1226> (Verification of Compendial Procedures <u>Specification</u> < 0.02 IU / bottle	Result: meets
Particle		
Test method	Light scattering in accordance with EP 2.9.19 <u>Specification</u> < 60 / bottle (particles ≥ 25µm) < 600 / bottle (particles ≥ 10µm)	Result: meets Result: meets
2. Sample bottle wrapped in steriBags		
Sterilization	Ethylene oxide	
Method	in accordance with EN ISO 11135:2020	
Provider	MEDICOPLAST International GmbH	
Run (Lot):	19472	
<u>Sterility test</u>	in accordance ISO 11138-2 and EP 5.1.1 <u>Specification</u> : sterile	Result: meets

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Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Das Zertifikat darf auszugsweise nicht ohne schriftliche Genehmigung der ACILA AG vervielfältigt werden.

The test results refer exclusively to the items tested. The certificate must not be copied partially without the approval of ACILA AG.

13. Konformitätserklärung || Revisionsdatum: 02.07.2025

O:\Konformitätserklärungen\5 Proben transport Probenaufbewahrung\Stericert Probengefäße\Glas\29822.1 STERICERT Probengefäße Kl. I - 100 ml M 47527 und M 48514 Tu.docx

ACILA AG
Opelstr. 14
64546 Mörfelden-Walldorf

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

Kreissparkasse Groß-Gerau
IBAN: DE57 5085 2553 0016 1514 74
BIC: HELADEF1GRG