

Postfach / P.O. box 1162  
 D-64320 Weiterstadt  
 Telefon: +49-(0)6151-8138-0  
 Telefax: +49-(0)6151-8138-15  
 Internet: [www.acila.com](http://www.acila.com)

## CERTIFICATE of CONFORMITY

Date of conformity:	2021-12-02
Product:	<b>STERICERT® Sample bottle double wrapped in SteriBags</b>
Volume:	1.000 ml
Product no.:	1960442/1960442-006
Lot no.:	28512
Expiry date:	2025-09-30

**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.

<b>Description</b>	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.	
<b>Material</b>	Bottle for infusion glass type II (ISO8536-1-A)	
Sample bottle	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)	
<b>Treatment and testing</b>		
<b>1. Sample bottle</b>		
<b>Sterilization Method</b>	Steam sterilisation in accordance with EP 5.1.1 and USP <1211>	
<b>Sterility test</b>	in accordance with EP 2.6.1 and USP <71> <u>Specification:</u> sterile <span style="float: right;">Result: meets</span>	
<b>Endotoxintest Method</b>	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 <u>Specification</u> <span style="float: right;"><u>Result</u></span>	
	< 0,001 I.E. /mL / < 0.001 IU / mL <span style="float: right;">meets</span>	
<b>Particle</b>		
Test method	Light scattering in accordance with EP 2.9.19 <u>Spezification</u>	
	< 0,3 / mL (particles ≥ 25µm) <span style="float: right;">meets</span>	
	< 2,5 / mL (particles ≥ 10µm) <span style="float: right;">meets</span>	
<b>2. Sample bottle double wrapped in steriBags</b>		
<b>Sterilization Method</b>	Ethylene oxide in accordance with EN ISO 11135:2020	
Provider	MEDICOPLAST International GmbH	
Run (Lot):	19308	
<b>Sterility test</b>	in accordance ISO 11138-2 and EP 5.1.1 <u>Specification:</u> sterile <span style="float: right;">Result: meets</span>	

The document has been generated electronically and is valid without a signature

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: 07.12.2021

O:\Konformitätserklärungen\5 Probentransport Probenaufbewahrung\Stericert Probengefäße\Glas\28512 STERICERT Probengefäße K1.1 I - 1000 ml M 39778 Tu.docx

ACILA AG  
 Verwaltung & Vertrieb  
 Headquarter & Sales  
 Rudolf-Diesel-Strasse 32 a  
 D 64331 Weiterstadt  
 Vorstand: Dr. Peter Weidner  
 Amtsgericht Darmstadt: HRB 54830

ACILA AG  
 Produktion & Labor  
 Production & Contract Laboratory  
 Opelstrasse 14  
 D 64546 Mörfelden-Walldorf  
 Ust-ID: DE111632765  
 St.-Nr. 07 228 05535

Bankverbindungen:  
 Postbank:  
 IBAN: DE90 4401 0046 0632 4024 68  
 BIC: PBNKDEFF  
 Volksbank Darmstadt-Südhessen eG  
 IBAN: DE41 5089 0000 0063 1614 03  
 BIC: GENODEF1VBD