

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

CERTIFICATE of CONFORMITY

Date of conformity:	2020-08-27
Product:	STERICERT® Probengefäß / sample bottle doppelt verpackt in SteriBags / double wrapped in SteriBags
Volume:	1.000 ml
Product no.:	1960442/1960442-006
Lot no.:	27970
Expiry date:	2024-05-31

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.

Material	
Sample vial	Bottle for injections glass type II in accordance with EP 3.2.1 und / and USP <661>
Stopper	Chlorobutyl rubber stopper for multiple piercing type I in accordance with EP 3.2.9 and USP <381> in accordance with DIN 8362 part 2
Cap	Flip cap in accordance with DIN ISO 8362.3
Content	5 ml water for injection in accordance with EP und / and USP
Sterility Bottle	
Method	Steam sterilisation in accordance with EP 5.1.1 and USP <1211>
Sterility test	sterile in accordance with EP 2.6.1 and USP <71>
SterBag	
Method	in accordance with EN ISO 13485:2016 / EN ISO 11135:2014
Endotoxin	
Test method	kinetic turbidimetric LAL-test - Ph. Eur.2.6.14, Method C - USP <85> - ANSI/AAMI ST72:2011 (Bacterial endotoxins- test methods, routine monitoring and alternatives to batch testing) - USP <1225> (Validation of Compendial Procedures) - USP <1226> (Verification of Compendial Procedures)
	<u>Specification</u> <u>Result</u>
	< 0,001 I.E. /mL / < 0.001 IU / mL meets
Particle	
Test method	Light scattering in accordance with EP 2.9.19
	<u>Specification</u> <u>Result</u>
	< 0,3 / mL (particles ≥ 25µm) meets
	< 2,5 / mL (particles ≥ 10µm) meets

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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: 27.08.2020

O:\Konformitätserklärungen\5 Probentransport Probenaufbewahrung\Stericert Probengefäße\Glas\27970 STERICERT Probengefäße K.I.I I - 1000 ml M 36469 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. 0722805535

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