

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 19 May 2023

Product Name		CLEARKLENS TEGO 2000SS VH25S	
Product Code	7516427		
Batch Number	FMP23118	56879	
Production Date	28/04/2023		
Expiration Date	EXP 28/10/2024		

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limi	ts	Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	6.2	8.2	7.7
Specific Gravity (20°C)	DM004	0.980	1.020	0.996

On behalf of Diversey site	Name:	Justyna Staron	Sabcho Svetoslavov
Quality Manger	Position	Quality	Control Inspector

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COA Template Version: 04 Date of	of issuing: March 11th 2019
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-37219A

 Product Code
 Lot Number
 Quantity
 UOM

 TEGO 2000SS BLK1 DV4767
 56879 - FMP23118
 125 Case

Validation Reference Number: 4767

TEGO 2000SS BLK1 DV4767 56879 - FMP23118, 3 X SAMPLES 3 Case

Validation Reference Number: 4767

Processing Run Start Date: 16-May-2023 9:15 AM
Processing Run End Date: 17-May-2023 2:57 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 28.1

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 41.4

PO Number: 405227

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 17-May-2023 3:58 AM

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company Brunel Close Drayton Fields Industrial Estate Daventry Northants NN11 8RB

Phone: + 44(0) 1327 706 111

Document ID: 143326

N/A Last Revised in Rel 2.0.0.0 Rel Date: 13-Aug-2018 Page 1 of 1

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mrs. Olga Kirchner

Report of Tests on: Tego 2000SS

Sample Description: Sample Code: Fmp23118 56879

Lucideon Sample Number: UK231863-12537

Lucideon Report Number: UK231863-12537/MFEP Issue Number: 1

Date Logged: 22-May-2023 Order Number: 405328

Date Reported: 20-Jun-2023 **Date(s) of Test(s)**: 06-Jun-2023 **to** 20-Jun-2023

Sterility Testing
Membrane Filtration EP

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

DocuSigned by:

Natalie Boot

Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 20 June 2023 | 14:16 BST 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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Natalie.Boot@uk.lucideon.com

IP Address: 86.188.245.148

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Notary Events	Signature	Timestamp
Notary Events Envelope Summary Events	Signature Status	Timestamps
Notary Events Envelope Summary Events Envelope Sent	Signature Status Hashed/Encrypted	Timestamps 20-Jun-23 14:15
Notary Events Envelope Summary Events Envelope Sent Certified Delivered	Signature Status Hashed/Encrypted Security Checked	Timestamps 20-Jun-23 14:15 20-Jun-23 14:15