

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 06 February 2024

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP24008	59413	
Production Date	08/01/2024		
Expiration Date	EXP 08/01/2027		

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	Limits		Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
Specific Gravity (20°C)	DM004	0.993	1.003	1.000
pH (neat solution)	DM001	7.5	8.5	8.2

On behalf of Diversey site Quality Manger	Name:	Angelíka Píetraszko Justyna Staron
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

1COA TEMPINATE VEISION . WATCH FINIT 2019	COA Template	Version : 04	Date 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

2173-43708A

Product Code

Lot Number

Quantity

UOM

TEGO 2000SC DV4724

59413

152 Case

Validation Reference Number:

4724

TEGO 2000SC DV4724

59413, SAMPLE BOX

1 Case

Validation Reference Number:

Processing Run Start Date: 27-Jan-2024 10:22 PM

Processing Run End Date: 28-Jan-2024 6:00 AM

Specified Dose Range (kGy):

25.0 - 45.0

Calculated Min Dose (kGy):

31.0

Reference Dose Range (kGy):

29.4 - 40.5

Calculated Max Dose (kGy):

41.9

PO Number: 407271

Rev: 2

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

Gamma Process Run Approved by:

Date/Time Signed

Digitally signed by Date: 2024.01.29

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

Unsigned

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO: Mrs. Olga Kirchner

Tego 2000SC Report of Tests on:

Sample Description: Sample Code: Fmp24008 59413

Lucideon Sample Number: UK24432-2985

Lucideon Report Number: UK24432-2985/MFEP Issue Number:

Date Logged: 05-Feb-2024 Order Number: 407429

26-Feb-2024 Date(s) of Test(s): 08-Feb-2024 to 22-Feb-2024 **Date Reported:**

> **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: 26 February 2024 | 11:10 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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Natalie Boot

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Stoke-on-Trent, Staffordshire ST4 7LQ

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Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	26-Feb-24 11:09
Certified Delivered	Security Checked	26-Feb-24 11:10
Signing Complete	Security Checked	26-Feb-24 11:10
Completed	Security Checked	26-Feb-24 11:10
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