

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 2000SS VH25S		
<b>Product Code</b>	7516427		
Batch Number	FMP24017	59493	
<b>Production Date</b>	17/01/2024		
<b>Expiration Date</b>	EXP 17/07/2025		

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	<b>Test Method</b>	Limi	ts	Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	6.2	8.2	7.8
Specific Gravity (20°C)	DM004	0.980	1.020	0.996

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 2173-43844A

Product Code Lot Number Quantity UOM
TEGO 2000SS BLK1 DV4767 59493 124 Case

Validation Reference Number: 4767

TEGO 2000SS BLK1 DV4767 59493, 3 x samples 3 Case

Validation Reference Number: 4767

Processing Run Start Date: 27-Jan-2024 9:36 PM
Processing Run End Date: 28-Jan-2024 5:24 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 27.9

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 41.5

PO Number: 407359

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

#### Gamma Process Run Approval authorized by STERIS

Date/Time: 28-Jan-2024 6:41 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: 165596

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 LA14XS

FAO: Mrs. Olga Kirchner

Report of Tests on: **Tego 2000SS** 

Sample Description: Sample Code: Fmp24017 59493

Lucideon Sample Number: UK24432-2984

Lucideon Report Number: UK24432-2984/MFEP Issue Number:

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

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

> **Sterility Testing** Membrane Filtration EP

Result: Pass

Test Results:

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

**End of Test Report** 

DocuSigned by:

Notalie 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

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## **DocuSign**

#### **Certificate Of Completion**

Envelope ld: 53231B2BF7ED42B4BB6A19B5BA993898 Subject: Complete with DocuSign: DataWindow.xps

Source Envelope:

Document Pages: 2

Certificate Pages: 1 AutoNav: Enabled

Envelopeld Stamping: Disabled

Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Status: Completed

Envelope Originator:

Natalie Boot

Queens Road

Stoke-on-Trent, Staffordshire ST4 7LQ

Natalie.Boot@uk.lucideon.com IP Address: 86.188.222.148

#### **Record Tracking**

Status: Original

26-Feb-24 | 11:08

Holder: Natalie Boot

Signatures: 2

Initials: 0

Natalie.Boot@uk.lucideon.com

Location: DocuSign

Sent: 26-Feb-24 | 11:09

Viewed: 26-Feb-24 | 11:10

Signed: 26-Feb-24 | 11:10

**Timestamp** 

Timestamp

### Signer Events

Natalie Boot natalie.boot@uk.lucideon.com

PlaceHolder

Lucideon Limited

Security Level: Email, Account Authentication (Required), Authentication, Logged in

# Signature

Notalie Boot

Signature Adoption: Pre-selected Style

Signature ID:

Signature

90369E90-4813-4123-B65D-5E8FBD375BF3

Using IP Address: 86.188.222.148

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab): I have reviewed this document I have reviewed this document

## **Electronic Record and Signature Disclosure:**

Not Offered via DocuSign In Person Signer Events

Payment Events	Status	Timestamps
Completed	Security Checked	26-Feb-24   11:10
Signing Complete	Security Checked	26-Feb-24   11:10
Certified Delivered	Security Checked	26-Feb-24   11:10
Envelope Sent	Hashed/Encrypted	26-Feb-24   11:09
Envelope Summary Events	Status	Timestamps
Notary Events	Signature	Timestamp
Witness Events	Signature	Timestamp
Carbon Copy Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
ntermediary Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Editor Delivery Events	Status	Timestamp
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