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## CERTIFICATE OF ANALYSIS

Date: 25 March 2025

<b>Product Name</b>	CLEARKLENS TEGO 2000SC VH25		
<b>Product Code</b>	101107744		
<b>Batch Number</b>	FMP25063	61844	
<b>Production Date</b>	04/03/2025		
<b>Expiration Date</b>	EXP 04/03/2028		

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	8.1

On behalf of Diversey site Quality Manger	Name:	Justyna Staron      Natalia Traichel
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

COA Template	Version : 04	Date of issuing : March 11th 2019
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# 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 2000SC

**Sample Description:** Sample Code: Fmp25063 61844

**Lucideon Sample Number:** N251311 - 2

**Lucideon Report Number:** N251311 - 2/MFEP

**Issue Number:** 1

**Date Logged:** 26-Mar-2025

**Order Number:** 410298

**Date Reported:** 15-Apr-2025

**Date(s) of Test(s):** 31-Mar-2025 to 14-Apr-2025

### 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**

Signed by:

*Tracy Wheeler*

Signer Name: Tracy Wheeler

Signing Reason: I have reviewed this document

Signing Time: 15 April 2025 | 15:09 BST

D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler

**Business Support Administrator**

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

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### Certificate Of Completion

Envelope Id: 3BB7804B-CBF6-466D-8D04-24397D8FBAD3	Status: Completed
Subject: N251311 Flexible Medical	
Source Envelope:	
Document Pages: 2	Signatures: 2
Certificate Pages: 1	Initials: 0
AutoNav: Enabled	Envelope Originator:
Enveloped Stamping: Disabled	Tracy Wheeler
Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London	Queens Road
	Stoke-on-Trent, Staffordshire ST4 7LQ
	Tracy.Wheeler@uk.lucideon.com
	IP Address: 86.188.222.148

### Record Tracking

Status: Original	Holder: Tracy Wheeler	Location: DocuSign
15-Apr-25   15:07	Tracy.Wheeler@uk.lucideon.com	

### Signer Events

Tracy Wheeler  
 tracy.wheeler@uk.lucideon.com  
 Placeholder  
 Lucideon Limited  
 Security Level: Email, Account Authentication (Required), Authentication, Login with SSO

### Signature

*Tracy Wheeler*

Signature Adoption: Pre-selected Style  
 Signature ID:  
 D85AB024-6E18-4F31-821E-2EC1AFA6CA90  
 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

### Timestamp

Sent: 15-Apr-25 | 15:08  
 Viewed: 15-Apr-25 | 15:08  
 Signed: 15-Apr-25 | 15:09

**Electronic Record and Signature Disclosure:**  
 Not Offered via Docusign

### In Person Signer Events

### Signature

### Timestamp

### Editor Delivery Events

### Status

### Timestamp

### Agent Delivery Events

### Status

### Timestamp

### Intermediary Delivery Events

### Status

### Timestamp

### Certified Delivery Events

### Status

### Timestamp

### Carbon Copy Events

### Status

### Timestamp

### Witness Events

### Signature

### Timestamp

### Notary Events

### Signature

### Timestamp

### Envelope Summary Events

### Status

### Timestamps

Envelope Sent	Hashed/Encrypted	15-Apr-25   15:08
Certified Delivered	Security Checked	15-Apr-25   15:08
Signing Complete	Security Checked	15-Apr-25   15:09
Completed	Security Checked	15-Apr-25   15:09

### Payment Events

### Status

### Timestamps

# STERIS: Gamma Certificate Of Processing

Prepared For FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-54850A

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<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	61844- STR002279	53	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	61844- STR002279 including x1 sample	53	Case
Validation Reference Number: 4724			

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Processing Run Start Date 18-Mar-2025 7:09 AM

Processing Run End Date 18-Mar-2025 9:36 PM

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<b>Specified Dose Range (kGy)</b>	<b>25.0 - 45.0</b>	<b>Calculated Min Dose (kGy)</b>	<b>28.5</b>
<b>Reference Dose Range (kGy)</b>	<b>29.4 - 40.5</b>	<b>Calculated Max Dose (kGy)</b>	<b>37.6</b>

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PO Number: 410228

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

**Gamma Process Run Approval authorized by STERIS**

DateTime Esigned 19-Mar-2025 7:00 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