

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: 24302 61251

Lucideon Sample Number: UK243983-27013

Lucideon Report Number: UK243983-27013/MFEP **Issue Number:** 1

Date Logged: 25-Nov-2024 **Order Number:** 409461

Date Reported: 16-Dec-2024 **Date(s) of Test(s):** 26-Nov-2024 to 14-Dec-2024

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:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 16 December 2024 | 12:13 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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Certificate Of Completion

| | |
|--|---------------------------------------|
| Envelope Id: ED648BC3-EBB3-4C4C-9AB8-4DBFA44AE94A | Status: Completed |
| Subject: sign | |
| Source Envelope: | |
| Document Pages: 1 | Signatures: 1 |
| Certificate Pages: 1 | Initials: 0 |
| AutoNav: Enabled | Envelope Originator: |
| Envelopeld Stamping: Disabled | Natalie Boot |
| Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London | Queens Road |
| | Stoke-on-Trent, Staffordshire ST4 7LQ |
| | Natalie.Boot@uk.lucideon.com |
| | IP Address: 86.188.222.148 |

Record Tracking

| | | |
|-------------------|------------------------------|--------------------|
| Status: Original | Holder: Natalie Boot | Location: DocuSign |
| 16-Dec-24 12:12 | Natalie.Boot@uk.lucideon.com | |

Signer Events

| Signer Events | Signature | Timestamp |
|--|---|---------------------------|
| Natalie Boot | <i>Natalie Boot</i> | Sent: 16-Dec-24 12:13 |
| natalie.boot@uk.lucideon.com | | Viewed: 16-Dec-24 12:13 |
| Admin Supervisor Placeholder | | Signed: 16-Dec-24 12:13 |
| Lucideon Limited | Signature Adoption: Pre-selected Style | |
| Security Level: Email, Account Authentication (Required), Authentication, Login with SSO | Signature ID: 90369E90-4813-4123-B65D-5E8FBD375BF3 | |
| | Using IP Address: 86.188.245.148 | |
| | With Signing Authentication via DocuSign password | |
| | With Signing Reasons (on each tab): | |
| | I have reviewed this document | |

Electronic Record and Signature Disclosure:
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| In Person Signer Events | Signature | Timestamp |
|------------------------------|------------------|-------------------|
| Editor Delivery Events | Status | Timestamp |
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| 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 | 16-Dec-24 12:13 |
| Certified Delivered | Security Checked | 16-Dec-24 12:13 |
| Signing Complete | Security Checked | 16-Dec-24 12:13 |
| Completed | Security Checked | 16-Dec-24 12:13 |
| Payment Events | Status | Timestamps |



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CERTIFICATE OF ANALYSIS

Date: 21 November 2024

| | | | |
|------------------------|-----------------------------|-------|--|
| Product Name | CLEARKLENS TEGO 2000SC VH25 | | |
| Product Code | 100868202 | | |
| Batch Number | FMP24302 | 61251 | |
| Production Date | 28/10/2024 | | |
| Expiration Date | EXP 28/10/2027 | | |

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 | 8.0 |

| | | |
|--|----------|---------------------------------------|
| On behalf of Diversey site Quality Manger | Name: | Justyna Staron Angelika Pietraszko |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

| | | |
|--------------|--------------|-----------------------------------|
| COA Template | Version : 04 | Date of issuing : March 11th 2019 |
|--------------|--------------|-----------------------------------|

STERIS: Gamma Certificate Of Processing

Prepared For FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-51835A

| <u>Product Code</u> | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|-----------------------------------|----------------------------|-----------------|------------|
| TEGO 2000SC DV4724 | 61251- STR001930 | 138 | Case |
| Validation Reference Number: 4724 | | | |
| TEGO 2000SC DV4724 | 61251- STR001930 X1 SAMPLE | 1 | Case |
| Validation Reference Number: 4724 | | | |

Processing Run Start Date 13-Nov-2024 2:20 AM

Processing Run End Date 13-Nov-2024 12:32 PM

| | | | |
|----------------------------|-------------|---------------------------|------|
| Specified Dose Range (kGy) | 25.0 - 45.0 | Calculated Min Dose (kGy) | 30.0 |
| Reference Dose Range (kGy) | 29.4 - 40.5 | Calculated Max Dose (kGy) | 40.3 |

PO Number: 409350

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

Signature Manifest

Reviewed and E-Signed By: **Tamas Szatmari (Quality Engineer)**

Date/Time Esigned 14-Nov-2024 11:57 AM

Document Content Revision 1

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