

# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-29479A

| <u>Product Code</u>               | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|-----------------------------------|-------------------|-----------------|------------|
| TEGO 2000SC DV4724                | 55198             | 30              | Case       |
| Validation Reference Number: 4724 |                   |                 |            |
| TEGO 2000SC DV4724                | 55198, SAMPLE BOX | 1               | Case       |
| Validation Reference Number: 4724 |                   |                 |            |

Processing Run Start Date: 11-Jul-2022 1:07 AM

Processing Run End Date: 11-Jul-2022 8:58 AM

|                             |             |                            |      |
|-----------------------------|-------------|----------------------------|------|
| 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): | 39.8 |

PO Number: 402719

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

## Signature Manifest

Reviewed and E-Signed By: **Nelia Dias (Quality Engineer)**

Date/Time E-Signed: 12-Jul-2022 7:55 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

# PHARMACEUTICAL ANALYSIS REPORT

**LUCIDEON**

insight creating advantage

## 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: Fmp22138 55198

**Lucideon Sample Number:** UK222981-19126

**Lucideon Report Number:** UK222981-19126/MFEP **Issue Number:** 1

**Date Logged:** 22-Jul-2022 **Order Number:** 403077

**Date Reported:** 12-Aug-2022 **Date(s) of Test(s):** 26-Jul-2022 to 09-Aug-2022

### 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**

Natalie Boot 12-Aug-22

Mrs Natalie Boot

**Senior 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.

Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.

Lucideon Limited  
Queens Road, Penkhull  
Stoke-on-Trent  
Staffordshire ST4 7LQ

T +44 (0)1782 764428  
enquiries@lucideon.com  
www.lucideon.com



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427  
www.Diversey.com

## CERTIFICATE OF ANALYSIS

Date: 25 July 2022

|                 |                             |       |  |
|-----------------|-----------------------------|-------|--|
| Product Name    | CLEARKLENS TEGO 2000SC VH25 |       |  |
| Product Code    | 100868202                   |       |  |
| Batch Number    | FMP22138                    | 55198 |  |
| Production Date | 18/05/2022                  |       |  |
| Expiration Date | EXP 18/05/2025              |       |  |

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                    | 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 | 0.999                        |
| pH (neat solution)      | DM001       | 7.5                          | 8.5   | 7.8                          |

|  |          |   |
|--|----------|---|
| On behalf of Diversey site<br>Quality Manger | Name:    | Angelika Partynska    Urszula Haraburda |
|  | Position | Quality Control Inspector               |

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

|              |              |                                      |
|--------------|--------------|--------------------------------------|
| COA Template | Version : 02 | Date of issuing : November 24th 2017 |
|--------------|--------------|--------------------------------------|