



Diversey Europe Operations BV  
Maarssenbroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 26 January 2023

|                 |                             |       |  |
|-----------------|-----------------------------|-------|--|
| Product Name    | CLEARKLENS TEGO 2000SC VH25 |       |  |
| Product Code    | 100868202                   |       |  |
| Batch Number    | FMP23016                    | 56739 |  |
| Production Date | 16/01/2023                  |       |  |
| Expiration Date | EXP 16/01/2026              |       |  |

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   | 7.6                          |

|                                              |          |                                         |
|----------------------------------------------|----------|-----------------------------------------|
| On behalf of Diversey site<br>Quality Manger | Name:    | Urszula Haraburda    Angelika Partynska |
|                                              | 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 2173-34323A

| <u>Product Code</u>               | <u>Lot Number</u>            | <u>Quantity</u> | <u>UOM</u> |
|-----------------------------------|------------------------------|-----------------|------------|
| TEGO 2000SC DV4724                | 56739 - FMP23016             | 150             | Case       |
| Validation Reference Number: 4724 |                              |                 |            |
| TEGO 2000SC DV4724                | 56739 - FMP23016, SAMPLE BOX | 1               | Case       |
| Validation Reference Number: 4724 |                              |                 |            |

Processing Run Start Date: 23-Jan-2023 11:41 PM

Processing Run End Date: 24-Jan-2023 7:03 AM

|                             |             |                            |      |
|-----------------------------|-------------|----------------------------|------|
| Specified Dose Range (kGy): | 25.0 - 45.0 | Calculated Min Dose (kGy): | 28.8 |
| Reference Dose Range (kGy): | 29.4 - 40.5 | Calculated Max Dose (kGy): | 39.0 |

PO Number: 404331

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

## Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 24-Jan-2023 8:27 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

# PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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## 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: Fmp23016 56739

**Lucideon Sample Number:** UK23334-2345

**Lucideon Report Number:** UK23334-2345/MFEP

**Issue Number:** 1

**Date Logged:** 27-Jan-2023

**Order Number:** 404421

**Date Reported:** 17-Feb-2023

**Date(s) of Test(s):** 02-Feb-2023 to 16-Feb-2023

### 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**

*ReBook 17 Feb 23*

Mrs Natalie Boot

**Senior Business Support Administrator**

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

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