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## CERTIFICATE OF ANALYSIS

Date: 17/01/2019

|                 |                             |
|-----------------|-----------------------------|
| Product Name    | CLEARKLENS TEGO 2000SC VH25 |
| Product Code    | 100961418                   |
| Batch Number    | FMP18348.46551              |
| Production Date | 14/12/2018                  |
| Expiration Date | EXP14/12/2021               |

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                  | 0.998                        |
| pH (neat solution)      | DM001       | 7.5    | 8.5                    | 7.9                          |

|   |          |                           |
|---|----------|---------------------------|
| On behalf of Diversey site<br>Quality Manager | Name :   | El. Marabunda Putyuslo    |
|   | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

|              |              |  |
|--------------|--------------|--|
| COA Template | Version : 02 | Date of Issuing : November 24 <sup>th</sup> 2017 |
|--------------|--------------|--|



# Wickham Laboratories

Contract Analytical Services

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White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 18 Jan 2019  
**Date Tested:** 18 Feb 2019  
**Date Test Completed:** 11 Mar 2019  
**Purchase Order:** PO32429

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0046783/3  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 18/01/2019  
**Test Article:** Tego 2000SC  
**Sample Code:** FMP18348 46551  
**Batch Ref:** 614785  
**Qty Received:** 20 x 50mL Bottles

| Test   | Method Item | Result                                   |
|--|-------------|--|
| Sterility Test by Membrane Filtration (Steritest) Method       | MM107/00    | Pass                                     |
| Growth In Tryptone Soya Broth at 20-25°C after 14 days         | MM107/01    | No growth in two broths                  |
| Growth In Fluid Thioglycollate Medium at 30-35°C after 14 days | MM107/02    | No growth in two broths                  |
| Growth of Sub-culture in TSB at 20-25°C after 4 - 7 days       | MM107/07    | No growth in two broths                  |
| Growth of Sub-culture in THY at 30-35°C after 4 - 7 days       | MM107/08    | No growth in two broths                  |
| Volume Tested  | MM107/05    | 20 x 50 mL                               |
| Tested in Accordance with Ph Eur, USP & JP                     | MQ005/07    | EP 9.0 2.6.1, USP 41 <71> & JP XVII 4.06 |
| Product Standard Data Sheet                                    | FG047/psd   | FM08-02                                  |

Approval is provided by Electronic Signature. Their name and position is shown below.

BSc. CBiol MRSB

Date: 19 Mar 2019 10:05:15

Mrs P. Pham-Lengoc  
Documentation Manager – Microbiology

# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1052A

| <u>Product Code</u>               | <u>Lot Number</u>           | <u>Quantity</u> | <u>UOM</u> |
|-----------------------------------|-----------------------------|-----------------|------------|
| TEGO 2000SC DV4724                | FMP18348 46551              | 29              | Case       |
| Validation Reference Number: 4724 |                             |                 |            |
| TEGO 2000SC DV4724                | FMP18348 46551 INC 1 SAMPLE | 1               | Case       |
| Validation Reference Number: 4724 |                             |                 |            |

Processing Run Start Date: 01-Jan-19 10:42 PM

Processing Run End Date: 02-Jan-19 05:52 AM

|                             |             |                            |      |
|-----------------------------|-------------|----------------------------|------|
| Specified Dose Range (kGy): | 25.0 - 45.0 | Calculated Min Dose (kGy): | 27.2 |
| Reference Dose Range (kGy): | 29.4- 40.5  | Calculated Max Dose (kGy): | 36.1 |

Gamma Process Run Approval authorized by STERIS

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  
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Daventry  
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