

**Diversey Europe BV** 

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

## **CERTIFICATE OF ANALYSIS**

Date:18/3/13

| Product Name           | CLEARKLENS TEGO 2001SS VH24S |
|------------------------|------------------------------|
| Product Code           | 7513403                      |
| Batch Number           | FMP13052 33526               |
| <b>Production Date</b> | 02/20/3                      |
| Expiration Date        | 12/2013                      |

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 | Lin<br>Lower - | nits<br>Upper      | Results        |
|-------------------------|-------------|----------------|--------------------|----------------|
| Appearance              | Visual      |                | ntly Yellow<br>uid | Gellas 1, gold |
| pH 100% (20°C)          | JDM001      | 8.0            | 9.0                | 8.4            |
| Specific Gravity (20°C) | JDM004      | 0.980          | 1.020              | 1.001          |
|                         |             |                |                    |                |

| On hele of Discourse site                     | Name:    | CSESCOE, O. Lunchna       |
|---|----------|---------------------------|
| On behalf of Diversey site<br>Quality Manager | Position | Quality Control Inspector |

| This document being issued electronical | ly does not bear a signature |                                  |
|---|------------------------------|----------------------------------|
| COA 7513403                             | Version: 04                  | Date of issuing: April 19th 2012 |



http://www.synergyhealthplc.com

## Certificate of Irradiation

Date Issued: 14-Mar-2013

UK32S11008646-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

ISO 11137:2006 Sterilisation of Health Care Products ISO 9001:2008 Quality Management System ISO 13485:2012 Quality System - Medical Devices

Flexible Medical Packaging Ltd Unit 8, White Cross Ind Estate Hightown Lancaster Lancashire LA1 4XS UNITED KINGDOM

All in accordance with current Technical Agreement

## Order Information **Customer Reference Number:** P020007 **Product Description:** TEGO 2001 SS 25-45kGy Validation Reference: 4.0968 **Quantity Received:** 132 Customer Minimum Specification kGy: 25.0 FMP13052-33526 @03/06/13/00 Customer Maximum Specification kGy: 45.0 Customer Unit Lot/Batch Number: 127 X B/No.W033526 + 5 SAMPLES , 3 PLTS LOT 4 THURS 28.2.13 Shop Order Number: S11008646-1-1 Synergy Health Sales Part Reference: 1002758 **Irradiation Data** Date and Time of Irradiation: 00 Mar 2042 45-52

| Reference Dose Range kGy:    | 35.9 - 38.0 |  |
|------------------------------|-------------|--|
| Calculated Minimum Dose kGy: | 25.6        |  |
| Calculated Maximum Dose kGy: | 41.0        |  |
|                              |             |  |
|                              |             |  |
|                              |             |  |
|                              |             |  |
| Comments:                    |             |  |
|                              |             |  |
|                              |             |  |
|                              |             |  |



Wickham Laboratories Limited, Hoeford Point, Barwell Lane, Gosport Hampshire P013 0AU England

Telephone: +44(0)1329 226600 +44(0)1329 832511

Fax:

+44(0)1329 226688

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS Date Received:

18 Mar 2013

Date Tested:

27 Mar 2013

**Date Test Completed:** 

10 Apr 2013

**Purchase Order:** 

20115

## **CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 

0009421/1

Test Required:

00074217

Sterility Test by Membrane Filtration (Steritest)

Date Received:

18/03/2013

Test Article:

**TEGO 2001SS** 

Sample Code: Baich Ref:

-FMP 13052 33526

Qty Received:

20 x 900mL Bottles

| Sterility Test by Membrane | Test          |      |     |       |   |
|----------------------------|---------------|------|-----|-------|---|
|                            | Sterility Tes | t by | Men | nbran | e |

Method Item Result

Filtration (Steritest) Method Growth in Tryptone Soya Broth at 20-25°C after 14 days MM107/00 Pass

No growth in one broth

Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days

MM107/02

MM107/01

No growth in one broth

Volume Tested

MM107/05

20 x 50 mL

Product Standard Data Sheet

FG047/psd

FM09

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

Zins

Date: 12 Apr 2013 08:49:09

Mrs P. Pham-Lengoc, BSc, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0009421

Certificate of Analysis - OSMM

Print Number: P0009798

Page 1 of 1

