



Diversey Europe Operations BV

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3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 15/1/16

| | |
|-----------------|-----------------------------|
| Product Name | CLEARKLENS TEGO 2000SC VH25 |
| Product Code | 100868202 |
| Batch Number | FMP15336 39461 |
| Production Date | 02/12/2015 |
| Expiration Date | EXP 02/12/2018 |

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 |
| pH 100% (20°C) | JDM001 | 7.5 | 8.5 | 7.9 |
| Specific Gravity (20°C) | JDM004 | 0.993 | 1.003 | 0.998 |
| | | | | |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | C. Miscoe, P. Pantyisho |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

| | | |
|-------------|--------------|---|
| COA 7513387 | Version : 04 | Date of issuing : April 27 th 2012 |
|-------------|--------------|---|



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 10-Jan-2016

UK32S11537259-1-1

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

EN ISO 11137-1:2015 Sterilisation of Health Care Products

EN ISO 9001:2008 Quality Management System

EN 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

| | |
|--------------------------------------|---|
| Account Number: | 100432 |
| Synergy Health Sales Part Reference: | 1002722 |
| Customer Reference Number: | P025680 |
| Product Description: | DIVERSEY TEGO 2000SC 50ml 25-42kGy |
| Validation Reference: | 4.1970 |
| Quantity Received: | 98 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 42.0 |
| Customer Unit Lot/Batch Number: | 97 X BATCH NO FMP15336 39461 THURS 17TH DEC 2015 2 PLTS LOT 1 + 1 SAMPLE |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 10-Jan-2016 00:09 |
| Reference Dose Range kGy: | 32.7 - 33.0 |
| Calculated Minimum Dose kGy: | 26.5 |
| Calculated Maximum Dose kGy: | 36.4 |

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



Wickham Laboratories

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 15 Jan 2016
Date Tested: 21 Jan 2016
Date Test Completed: 09 Feb 2016
Purchase Order: 25792

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0026749/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:
PH Eur and USP
Date Received: 15/01/2016
Test Article: Tego 2000sc
Sample Code: FMP15336 39461
Batch Ref: 518692
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 |
| Product Standard Data Sheet | FG047/psd | FM08 |

Comments

Test carried out according to current Pharmacopoeias.

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

Date: 10 Feb 2016 12:52:08

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology