



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 27 05. 2016

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP 16128 40774
Production Date	04/05/2016
Expiration Date	EXP 04/05/2019

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)	DM001	7.5	8.5	8.0
Specific Gravity (20°C)	DM004	0.993	1.003	0.999

On behalf of Diversey site Quality Manager	Name :	
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 100868202	Version : 02	Date of issuing : April 7 <sup>th</sup> 2016
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# Wickham Laboratories

Contract Analytical Services

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

**Date Received:** 31 May 2016  
**Date Tested:** 07 Jun 2016  
**Date Test Completed:** 29 Jun 2016  
**Purchase Order:** 26697

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0029202/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 31/05/2016  
**Test Article:** TEGO 2000sc  
**Sample Code:** -  
**Batch Ref:** FMP16128 40774  
**Qty Received:** 20 x 50mL Bottles + 5 spare

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 8.0 2.6.1, USP 39 <71> & JP XVI 4.06
Product Standard Data Sheet	FG047/psd	FM08

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

Date: 30 Jun 2016 15:48:53

Mrs P. Pham-Lengoc  
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 20-May-2016

UK32S11622748-1-1

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:	P026560
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.1970
Quantity Received:	110
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	90 X FMP16126 40359 + 1 SAMPLE, 14 X FMP16128 40774 + 5 SAMPLES THURS 12TH MAY 2016 TOTAL 3 PLTS LOT

## Irradiation Data

Date and Time of Irradiation:	20-May-2016 07:04
Reference Dose Range kGy:	34.9 - 35.4
Calculated Minimum Dose kGy:	28.3
Calculated Maximum Dose kGy:	39.1

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