



Diversey Europe BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands  
Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 26/7/13

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	7513387
Batch Number	FMP13186 34175
Production Date	07/2013
Expiration Date	07/2015

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	7.7
Specific Gravity (20°C)	JDM004	0.993	1.003	1.001

On behalf of Diversey site Quality Manager	Name :	C. P. K. K. K. K. K.
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7513387	Version : 03	Date of issuing : November 28 <sup>th</sup> 2011
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<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 23-Jul-2013

UK32S11037619-1-1

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:	P020751
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.0716
Quantity Received:	448
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	446 X B/No.FMP13186 34175+ 2 SAMPLES , 9 PLTS LOT 4 THURS 18.7.13 Re issued 23.07.13
Shop Order Number:	S11037619-1-1
Synergy Health Sales Part Reference:	1002722

### Irradiation Data

Date and Time of Irradiation:	23-Jul-2013 02:27
Reference Dose Range kGy:	31.5 - 34.9
Calculated Minimum Dose kGy:	26.2
Calculated Maximum Dose kGy:	38.4

Irradiation Release Authorised By Synergy Health plc

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

contract analytical services

Wickham Laboratories Limited,  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 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:** 29 Jul 2013  
**Date Tested:** 14 Aug 2013  
**Date Test Completed:** 02 Sep 2013  
**Purchase Order:** 20798

## CERTIFICATE OF ANALYSIS

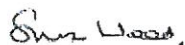
**Laboratory Reference Number:** 0011557/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I with Subculture: PH Eur and USP  
**Date Received:** 29/07/2013  
**Test Article:** TEGO 2000SC Block 1  
**Sample Code:** -  
**Batch Ref:** FMP13186 34175  
**Qty Received:** 20 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 Tryptone Soya Broth at 30-35°C after 4 days	MM107/07	No growth in two broths
Growth of Sub-culture in Fluid Thioglycollate at 20-25°C after 4 days	MM107/08	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM08

### Comments

As Steritest Sterility Test

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



Date: 05 Sep 2013 14:35:24

Mrs S.L. Wood, BSc (Hons), CBiol, MSB  
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0011557

Certificate of Analysis - OSMM

Print Number: P0013181

Page 1 of 1