



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 29.02.16

Product Name	CLEARLENs TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP16044 39803
Production Date	13/02/2016
Expiration Date	EXP 13/02/2019

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)	JDM001	7.5	8.5	7.8
Specific Gravity (20°C)	JDM004	0.993	1.003	0.998

On behalf of Diversey site Quality Manager	Name :	Polyester, H. Hinkel
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

COA 7513387	Version : 04	Date of issuing : April 27 <sup>th</sup> 2012
-------------	--------------	---



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 22-Feb-2016

UK32S11567231-1-1

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:	PO26002
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.1970
Quantity Received:	105
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	104 X BATCH NO: FMP16044 39803 + 1 SAMPLE THURS 18TH FEB 2016 2 PLTS LOT 2

## Irradiation Data

Date and Time of Irradiation:	21-Feb-2016 10:36
Reference Dose Range kGy:	33.9 - 34.4
Calculated Minimum Dose kGy:	27.5
Calculated Maximum Dose kGy:	38.0

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

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
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 Feb 2016  
**Date Tested:** 03 Mar 2016  
**Date Test Completed:** 25 Mar 2016  
**Purchase Order:** 26113

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0027551/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 29/02/2016  
**Test Article:** TEGO 2000sc  
**Sample Code:** FMP16044 39803  
**Batch Ref:** 523104  
**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 38 <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: 29 Mar 2016 13:43:48

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology