



Date: 14/8/13

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

On behalf of Diversey site Quality Manager	Name :	<i>Chloe Parry</i>
	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: 05-Aug-2013

UK32S11041383-1-1

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:	P020808
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.0716
Quantity Received:	299
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	297 X FMP13199 34532 - THURS 01.08.13 6PLTS PLUS 2 SAMPLES LOT 5
Shop Order Number:	S11041383-1-1
Synergy Health Sales Part Reference:	1002722

## Irradiation Data

Date and Time of Irradiation:	03-Aug-2013 14:40
Reference Dose Range kGy:	34.7 - 36.2
Calculated Minimum Dose kGy:	28.8
Calculated Maximum Dose kGy:	39.8

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:** 14 Aug 2013  
**Date Tested:** 21 Aug 2013  
**Date Test Completed:** 10 Sep 2013  
**Purchase Order:** 20866

## CERTIFICATE OF ANALYSIS

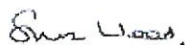
**Laboratory Reference Number:** 0011837/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I with Subculture: PH Eur and USP  
**Date Received:** 14/08/2013  
**Test Article:** TEGO 2000SC Block 1  
**Sample Code:** -  
**Batch Ref:** FMP 13199 34532  
**Qty Received:** 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 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: 11 Sep 2013 16:53:25

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

Consignment: 0011837

Certificate of Analysis - OSMM

Print Number: P0013291

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