



COA 7513387	Version : 04	Date of issuing : April 27 <sup>th</sup> 2012
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 19-Oct-2015

UK32S11485320-1-1

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:	PO25280
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.1970
Quantity Received:	211
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	TUES 13TH OCT 2015 4 PLTS + 2 SAMPLES
Other Process Details:	104 X BATCH NO: FMP15275 38954 + 1 SAMPLE, 105 X BATCH NO: FMP15281 39057 + 1 SAMPLE

## Irradiation Data

Date and Time of Irradiation:	18-Oct-2015 10:30
Reference Dose Range kGy:	33.5 - 35.6
Calculated Minimum Dose kGy:	27.2
Calculated Maximum Dose kGy:	39.3

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

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Ms D Henderson  
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White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 25 Nov 2015  
**Date Tested:** 28 Nov 2015  
**Date Test Completed:** 12 Dec 2015  
**Purchase Order:** 25335

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0025445/3  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I with Subculture: PH Eur and USP  
**Date Received:** 25/11/2015  
**Test Article:** TEGO 2000sc  
**Sample Code:** 512468  
**Batch Ref:** FMP 15281 39057  
**Qty Received:** 20 x 50mL Bottles + 10 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
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: 14 Dec 2015 14:37:41

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology