

COA 7513403	Version : 04	Date of issuing : April 19 <sup>th</sup> 2012
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 16-Feb-2015

UK32S11329987-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 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

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## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1002758
Customer Reference Number:	P023778
Product Description:	TEGO 2001 SS 25-45kGy
Validation Reference:	4.0968
Quantity Received:	120
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	115 X B/NO: FMP15040 37604 THURS 12 FEB 2015 LOT 3 2PLTS + 5 SAMPLES
Other Process Details:	Released against validation 4.1903. Calculated minimum dose 26.4 kGy and calculated maximum dose 40.3 kGy

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## Irradiation Data

Date and Time of Irradiation:	15-Feb-2015 07:46
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Irradiation Release Authorised By Synergy Health plc

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

**Date Received:** 24 Feb 2015  
**Date Tested:** 26 Feb 2015  
**Date Test Completed:** 20 Mar 2015  
**Purchase Order:** 23860

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0021335/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:  
PH Eur and USP  
**Date Received:** 24/02/2015  
**Test Article:** TEGO 2001ss  
**Sample Code:** -  
**Batch Ref:** FMP15040 37604  
**Qty Received:** 21 x 900mL 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 one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Growth of Sub-culture in TSB at 20-25°C after 4 - 7 days	MM107/07	No growth in one broth
Growth of Sub-culture in THY at 30-35°C after 4 - 7 days	MM107/08	No growth in one broth
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM09

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 23 Mar 2015 17:06:14

Mrs S.L. Wood  
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0021335

Certificate of Analysis - OSMM

Print Number: P0026268

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ISO  
17025

GLP GMP FDA

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