



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 8/7/15

Product Name	CLEARLENSS TEGO 2000SS VH25S
Product Code	7516428
Batch Number	FMP 15140 38440
Production Date	20/05/2015
Expiration Date	20/11/2016

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	6.2	8.2	7.5
Specific Gravity (20°C)	JDM004	0.990	1.010	0.994

On behalf of Diversey site Quality Manager	Name :	Poulysis, Mabuse
	Position	Quality Control Inspector

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

COA VH25S	Version : 05	Date of issuing : June 11 <sup>th</sup> 2013
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 06-Jul-2015

UK32S11419312-2-2

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:	P024463
Product Description:	TEGO 2001 SS 25-45kGy
Validation Reference:	4.1903
Quantity Received:	27
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	TEGO 2000SS, 23 X B/N FMP15140 38440 + 4 SAMPLES THURS 04 JUN 2015 TOTAL 2 PLTS LOT 1

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## Irradiation Data

Date and Time of Irradiation:	04-Jul-2015 03:15
Reference Dose Range kGy:	37.8 - 37.8
Calculated Minimum Dose kGy:	26.7
Calculated Maximum Dose kGy:	39.6

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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:** 09 Jul 2015  
**Date Tested:** 16 Jul 2015  
**Date Test Completed:** 30 Jul 2015  
**Purchase Order:** PO24687

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0023557/4  
**Test Required:** Membrane Filtration by Steritest  
**Date Received:** 09/07/2015  
**Test Article:** TEGO 2000ss  
**Sample Code:**  
**Batch Ref:** FMP15140 38440  
**Qty Received:** 20 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 two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM08

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

Date: 31 Jul 2015 13:19:12

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology