



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 6.09.2016

Product Name	CLEARLENs TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP16201-40914
Production Date	19/07/2016
Expiration Date	19/07/2019

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)	DM001	7.5	8.5	7.9
Specific Gravity (20°C)	DM004	0.993	1.003	1.000

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

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

COA 100868202	Version : 02	Date of issuing : April 7 <sup>th</sup> 2016
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# 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:** 07 Sep 2016  
**Date Tested:** 16 Sep 2016  
**Date Test Completed:** 05 Oct 2016  
**Purchase Order:** 27278

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0030973/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 07/09/2016  
**Test Article:** TEGO 2000sc  
**Sample Code:**  
**Batch Ref:** FMP16201 40914  
**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 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 39 <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: 06 Oct 2016 16:17:29

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 31-Aug-2016

UK33S11689924-1-1

This is to certify that AST Daventry 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:	1106751
Customer Reference Number:	P026987
Product Description:	TEGO 2000SC DV4724 25-45 kGy
Validation Reference:	4724
Quantity Received:	7
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	BATCH NO: FMP16201, 40914, INC 1 SAMPLE BOX, 1 PLT

## Irradiation Data

Date and Time of Irradiation:	29-Aug-2016 05:44
Reference Dose Range kGy:	38.0 - 38.0
Calculated Minimum Dose kGy:	32.3
Calculated Maximum Dose kGy:	42.2

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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