



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 25.08.2016

Product Name	CLEARLENs TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP 16196 41186
Production Date	14/07/2016
Expiration Date	EXP 14/07/2019

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 :	Pandjalis, J. Staver
	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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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 15-Aug-2016

UK33S11670115-1-1

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 25-42 kGy TRIPLE VALIDATION
Quantity Received:	98
Customer Unit Lot/Batch Number:	TRIPLE VALIDATION, DEV001930, FMP16196,41186, 2 plts
Other Process Details:	Actual Min Dose: 31.8kGy Actual max dose: 42.2kGy

## Irradiation Data

Date and Time of Irradiation:	15-Aug-2016 08:52
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Irradiation Release Authorised By Synergy Health plc

A2 190816 CE

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



# Wickham Laboratories

Contract Analytical Services

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Ms D Henderson  
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Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 25 Aug 2016  
**Date Tested:** 02 Sep 2016  
**Date Test Completed:** 16 Sep 2016  
**Purchase Order:** 27213

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0030769/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 25/08/2016  
**Test Article:** TEGO2000sc  
**Sample Code:** FMP16196  
**Batch Ref:** 41186  
**Qty Received:** 20 Bottles + 20 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
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: 19 Sep 2016 12:15:21

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology