



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427  
www.Diversey.com

## CERTIFICATE OF ANALYSIS

Date: 30/04/2019

Product Name	CLEARLEN S TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP 19091 47001
Production Date	01/04/2019
Expiration Date	EXP 01/04/2022

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
Specific Gravity (20°C)	DM004	0.993	1.003	0.998
pH (neat solution)	DM001	7.5	8.5	8.3

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

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of Issuing : November 24 <sup>th</sup> 2017
--------------	--------------	--



# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
Fax: +44(0)1329 226688

mail@wickhamlabs.co.uk  
www.wickhamlabs.co.uk

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

**Date Received:** 30 Apr 2019  
**Date Tested:** 28 May 2019  
**Date Test Completed:** 19 Jun 2019  
**Purchase Order:** 33025

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0048472/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 30/04/2019  
**Test Article:** Tego 2000SC  
**Sample Code:** FMP19091 47001  
**Batch Ref:** 626640  
**Qty Received:** 20 x 50mL Bottle + 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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 42 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM08-04

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

Date: 21 Jun 2019 15:08:26

Victoria Watson  
Laboratory Manager – Microbiology

# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-2704A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	FMP 19091 47001	106	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	FMP 19091 47001 INC 1 SAMPLE	1	Case
Validation Reference Number: 4724			

Processing Run Start Date: 23-Apr-19 01:00 AM

Processing Run End Date: 23-Apr-19 08:21 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	28.7
Reference Dose Range (kGy):	29.4- 40.5	Calculated Max Dose (kGy):	38.5

Gamma Process Run Approval authorized by STERIS

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

## Processing Location

Synergy Health Sterilisation UK  
Limited, a STERIS Company  
Brunel Close  
Drayton Fields Industrial Estate  
Daventry  
Northants  
NN11 8RB  
Phone: + 44(0) 1327 706 111