



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 15.05.2019

Product Name	CLEARLENS TEGO 2000SC VH25
Product Code	100961418
Batch Number	F1019101 47118
Production Date	11/04/2018
Expiration Date	EXP 11/04/2022

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	1.002
pH (neat solution)	DM001	7.5	8.5	8.0

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

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 th 2017
--------------	--------------	--



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hesford 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: 15 May 2019
Date Tested: 24 Jun 2019
Date Test Completed: 08 Jul 2019
Purchase Order: 33117

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0048716/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 15/05/2019
Test Article: Tego 2000SC
Sample Code: FMP19101 47118
Batch Ref: 634594
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
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.

 BSc. CBiol MRSB

Date: 10 Jul 2019 08:44:19

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-2869A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	FMP19101 47118	16	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	FMP19101 47118, INC 5 SMPLS	5	Case
Validation Reference Number: 4724			

Processing Run Start Date: 01-May-19 03:31 PM

Processing Run End Date: 01-May-19 10:25 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	28.3
Reference Dose Range (kGy):	29.4- 40.5	Calculated Max Dose (kGy):	37.0

Other Information

FMP19101 47118, INC 5 SAMPLES, 1 PLT

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