



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: 23 May 2019
Date Tested: 09 Jul 2019
Date Test Completed: 31 Jul 2019
Purchase Order: PO33163

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0048856/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 23/05/2019
Test Article: Tego 2000SC
Sample Code: FMP19107 47180
Batch Ref: 630807
Qty Received: 20 x 50mL Bottles + 5 Spares

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	FM08-02

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

BSc. CBiol. MRSB

Date: 07 Aug 2019 12:16:02

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3029A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	FMP19107 47180	104	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	FMP19107 47180 1 X SAMPLE	1	Case
Validation Reference Number: 4724			

PO Number: PO33036

Processing Run Start Date: 12-May-19 05:49 AM

Processing Run End Date: 12-May-19 01:21 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	29.1
Reference Dose Range (kGy):	29.4- 40.5	Calculated Max Dose (kGy):	38.8

Signature Manifest

Reviewed and E-Signed By: Mark Morse (QA Officer)

Date/Time E-Signed: 2019-05-29 11:05 AM

Document Content Revision: 1

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



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Maarssebroeksedijk 2
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CERTIFICATE OF ANALYSIS

Date: 22/05/2019

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	100961418
Batch Number	FMP 19107 47180
Production Date	17/04/2019
Expiration Date	EXP 17/04/2022

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	8.2

On behalf of Diversey site Quality Manager	Name :	Reutylis J. Staan
	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
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