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CERTIFICATE OF ANALYSIS

Date: 30/10/2018

Product Name	**CLEARKLENS TEGO 2000SS VH25S**
Product Code	7516427
Batch Number	FMP 18285 46012
Production Date	12/10/2018
Expiration Date	EXP 12/04/2020

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 Lower - Upper		Results
Appearance	Visual	Clear Slightly Yellow Liquid		Clear Slightly Yellow Liquid
pH (neat solution)	DM001	6.2	8.2	7.5
Specific Gravity (20°C)	DM004	0.990	1.010	1.000

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

This document being issued electronically does not bear a signature

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

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

Date Received: 31 Oct 2018
Date Tested: 08 Nov 2018
Date Test Completed: 27 Nov 2018
Purchase Order: 32019

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0045552/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 31/10/2018
Test Article: Tego 2000SS
Sample Code: FMP18285 46012
Batch Ref: 9673
Qty Received: 20 x 900mL Bottles + 2 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 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM08-02

Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

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

BSc. CBiol. MRSB

Date: 29 Nov 2018 11:50:23

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

GMP GLP FDA

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 24-Oct-2018 **UK33S12184414-4-1**

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1111557
Customer Reference Number:	P031918
Product Description:	TEGO 2000SS BLK1 DV4767 25-45KGY
Validation Reference:	4767
Quantity Received:	124
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18285 46012, INC 6 SMPLS, 2 PLTS

Irradiation Data

Date and Time of Irradiation:	24-Oct-2018 04:06
Reference Dose Range kGy:	34.8 - 35.2
Calculated Minimum Dose kGy:	27.6
Calculated Maximum Dose kGy:	39.9

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company A3