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CERTIFICATE OF ANALYSIS

Date: 28.11.18

Product Name	**CLEARKLENS TEGO 2000SS VH25S**
Product Code	7516427
Batch Number	FHP 18 309 46225
Production Date	05/11/2018
Expiration Date	Exp 05/05/2020

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	Limits 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	0.996

On behalf of Diversey site Quality Manager	Name :	apa. Kirchner, Partyusz
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-777A

Product Code	Lot Number	Quantity	UOM
TEGO 2000SS BLK1 DV4767	FMP18309	295	Case
Validation Reference Number:	4767		
TEGO 2000SS BLK1 DV4767	FMP18309 SAMPLES	5	Case
Validation Reference Number:	4767		

Processing Run Start Date: 20-Nov-18 08:21 AM

Processing Run End Date: 20-Nov-18 05:45 PM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**26.7**
Reference Dose Range (kGy):	**31.5- 39.7**	**Calculated Max Dose (kGy):**	**39.9**

Other Information

FMP18309 46225, INC 5 SAMPLES, 6 PLTS

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

STERIS: Gamma Dosimetry Record

Run ID: 2173-777A

FLEXIBLE MEDICAL PACKAGING LTD (8245)

Irradiator / Method: IR-150 Hydraulic Irradiator - ON-STD

Carrier-Seq	Coordinate	Batch (Cal Date)	Spectro S/N	Micro S/N	Absorbance	Thickness	Final Dose (kGy)	Comment
1-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.853	2.8451	35.2	
17-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.906	3.0612	34.2	
34-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.902	3.0721	33.6	
50-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.865	2.8939	34.9	

Minimum Reference Dose for Record (kGy): 33.6

Maximum Reference Dose for Record (kGy): 35.2

Last Dosimeter Measurement Date: 2018-11-21 01:04 AM

Signature Manifest

Prepared By: **Andrian Perju (Operator)**

Date/Time E-Signed: 2018-11-21 01:04 AM

Document Content Revision: 1

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Synergy Health Sterilisation UK Limited, a STERIS Company
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Comment Legend: OUT = Calculated Dose Outside Allowable Limits Provided By Process Specification

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: 29 Nov 2018
Date Tested: 05 Dec 2018
Date Test Completed: 19 Dec 2018
Purchase Order: 32214

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0046063/3
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 29/11/2018
Test Article: Tego 2000SS
Sample Code: FMP18309 46225
Batch Ref: 9743
Qty Received: 20 x 900mL Bottles + 4 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 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.

CBiol MRSB

Date: 20 Dec 2018 16:28:24

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology