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CERTIFICATE OF ANALYSIS

Date: 07/01/2019

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	100961418
Batch Number	FMP18344 46317
Production Date	10/12/2018
Expiration Date	EXP 10/12/2021

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	7.7

On behalf of Diversey site Quality Manager	Name :	J. Stansen
	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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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1006A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	FMP18344 46317	20	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	FMP18344 46317 SAMPLE	1	Case
Validation Reference Number: 4724			

Processing Run Start Date: 19-Dec-18 05:49 AM

Processing Run End Date: 19-Dec-18 03:43 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	30.7
Reference Dose Range (kGy):	29.4- 40.5	Calculated Max Dose (kGy):	41.3

Other Information

FMP18344 46317, INC 1 SMPL, 1 PLT

Gamma Process Run Approval authorized by STERIS

A2

09-Jan-2019

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

Document ID: 10315

Last Revised in Rel 2.0.0.0

Rel Date: 08/13/2018

Page 1 of 1

STERIS: Gamma Dosimetry Record
FLEXIBLE MEDICAL PACKAGING LTD (8245)
Irradiator / Method: IR-150 Hydraulic Irradiator - ON-STD

Run ID: 2173-1006A

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	0.876	2.8866	36.1	
2-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.838	2.7234	37.2	

Minimum Reference Dose for Record (kGy): 36.1
Maximum Reference Dose for Record (kGy): 37.2

Last Dosimeter Measurement Date: 2018-12-19 11:44 PM

Signature Manifest

Prepared By: Steve Brown (Operator)

Date/Time E-Signed: 2018-12-19 11:45 PM

Document Content Revision: 1

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



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www.wickhamlabs.co.uk

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

Date Received: 08 Jan 2019
Date Tested: 23 Jan 2019
Date Test Completed: 13 Feb 2019
Purchase Order: 32357

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0046602/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 08/01/2019
Test Article: Tego 2000SC
Sample Code: FMP18344 46317
Batch Ref: 614785
Qty Received: 20 x 50mL Bottles + 5 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

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

C Biol MRSB

Date: 15 Feb 2019 16:42:56

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

CERTIFICATE OF CONFORMANCE

TO:
Diversey Ltd
Amber Park Distribution Centre
Highview Road
South Normanton, Alfreton
Derbyshire
DE55 2DT

Page : 1

DATE : 11/01/19
DESPATCH NO : DN40588
FMP ORDER NUMBER : SO31367
CUSTOMER REFERENCE : 4702311649/100961418

LINE	PART NUMBER	CUSTOMER REFERENCE	QUANTITY	UNIT	LOT REF	LOT LINE
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1	DEV000902	100961418	20	EA	WO46317	
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PRODUCT: TEGO 2000SC SOLUTION 50ML
DAV- ITEM: 1106751/ DOSE: 25-42KGY / VAL:4724
NO OF CARTONS:
BLOCK 1 - 7513387
QA will add to the Diversey database, CofA, CofI, &
Sterility test certs.
only when all testing completed & uploaded to JD database

CERTIFICATE OF CONFORMANCE

These goods have been manufactured in accordance with FMP Quality Systems (ISO13485:2016) and to the agreed specification. Responsibility for release of sterile products remains with the customer. Customers are responsible for ensuring the fitness for the purpose of the goods supplied.

FOR AND ON BEHALF OF FMP Q.A. DEPARTMENT: *apa barcha*

DATE: *17/02/19*