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CERTIFICATE OF ANALYSIS

Date: 02 July 2021

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP21141	51932	
Production Date	21/05/2021		
Expiration Date	EXP 21/05/2024		

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	0.999
pH (neat solution)	DM001	7.5	8.5	8.0

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda Angelika Partynska
	Position	Quality Control Inspector

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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: 2173-20340A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	WO51932	142	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	WO51932, SAMPLE BOX	1	Case
Validation Reference Number: 4724			

Processing Run Start Date: 20-Jun-2021 6:35 PM

Processing Run End Date: 21-Jun-2021 1:58 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.7
Reference Dose Range (kGy):	29.4 - 40.5	Calculated Max Dose (kGy):	37.6

PO Number: 400053

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

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

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Tego 2000 SC

Sample Description: Sample Code: Fmp21141 51932

Lucideon Sample Number: UK212880-19592

Lucideon Report Number: UK212880-19592/MFEP **Issue Number:** 1

Date Logged: 05-Jul-2021 **Order Number:** PO 400228

Date Reported: 23-Jul-2021 **Date(s) of Test(s):** 07-Jul-2021 to 21-Jul-2021

Sterility Testing

Membrane Filtration EP


Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report


23 JUL 21

Mrs Andrea Saunders
Business Support Administrator

Page 1 of 1

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