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CERTIFICATE OF ANALYSIS

Date:

02 March 2021

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP21041	51306	
Production Date	10/02/2021		
Expiration Date	EXP 10/02/2024		

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	1.003
pH (neat solution)	DM001	7.5	8.5	8.2

On behalf of Diversey site Quality Manger	Name:	urszula Haraburda Ewelina Markiel
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-17253A

<u>Product Code</u> <u>Lot Number</u> <u>Quantity</u> <u>UOM</u>

TEGO 2000SC DV4724 WO51306 51 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 WO51306, SAMPLE BOX 1 Case

Validation Reference Number: 4724

Processing Run Start Date: 23-Feb-21 07:43 AM

Processing Run End Date: 23-Feb-21 03:47 PM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 28.8

Reference Dose Range (kGy): 29.4 - 40.5 Calculated Max Dose (kGy): 38.6

PO Number: 37468

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

Document ID: 72425

Rel Date: 08/13/2018

Last Revised in Rel 2.0.0.0

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000 SC

Sample Description:

Sample Code: Fmp21041 51306

Lucideon Sample Number: UK21923-6233

Lucideon Report Number: UK21923-6233/MFEP

Issue Number:

1

Date Logged:

03-Mar-2021

Order Number:

PO 37566

Date Reported:

24-Mar-2021

Date(s) of Test(s):

10-Mar-2021 to 24-Mar-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

NCBOOK 24-MOL-51

Mrs Natalie Boot

Business Support Administrator

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