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CERTIFICATE OF ANALYSIS

Date:

21 April 2021

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP21083	51564	
Production Date	24/03/2021		
Expiration Date	EXP 24/09/2022		

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 Method	Limi Lower	- Upper	Results
Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
DM001	6,2	8.2	7.4
DM004	0.980	1.020	0.997
	Visual DM001	Visual Clear Slightly DM001 6.2	Visual Clear Slightly Yellow Liquid DM001 6.2 8.2

On behalf of Diversey site Quality Manger	Name:	Angelika Partynska Justyna Staron
	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: 2173-18448A

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

TEGO 2000SS BLK1 DV4767 WO51564 53 Case

Validation Reference Number: 4767

TEGO 2000SS BLK1 DV4767 WO51564, INC 3 SMPLS 53 Case

Validation Reference Number: 4767

Processing Run Start Date: 13-Apr-21 03:24 AM

Processing Run End Date: 13-Apr-21 10:36 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 25.7

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 38.4

PO Number: 37798

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: 76188

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 SS

Sample Description:

Sample Code: Fmp21083 51564

Lucideon Sample Number: UK211750-12226

Lucideon Report Number: UK211750-12226/MFEP

Issue Number:

Date Logged:

22-Apr-2021

Order Number:

PO 37894

Date Reported:

24-May-2021

Date(s) of Test(s):

07-May-2021 to 21-May-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

Mrs Andrea Saunders

Business Support Administrator

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