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CERTIFICATE OF ANALYSIS

Date:

01 July 2022

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP22124	54514	
Production Date	04/05/2022		
Expiration Date	EXP 04/11/2023		

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
pH (neat solution)	DM001	6.2	8.2	7.4
Specific Gravity (20°C)	DM004	0.980	1.020	0.999

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Angelika Partynska
	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 2173-29021A

 Product Code
 Lot Number
 Quantity
 UOM

 TEGO 2000SS BLK1 DV4767
 54514 - FMP22124
 102 Case

Validation Reference Number: 4767

TEGO 2000SS BLK1 DV4767 54514 - FMP22124, INC 3 SMPLS 3 Case

Validation Reference Number: 4767

Processing Run Start Date: 22-Jun-2022 10:45 PM
Processing Run End Date: 23-Jun-2022 9:49 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 27.3

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 40.4

PO Number: 402547

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

Signature Manifest

Reviewed and E-Signed By: Tamas Szatmari (Quality Engineer)

Date/Time E-Signed: 24-Jun-2022 8:38 AM

Document Content Revision: 1

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: 115130

N/A Last Revised in Rel 2.0.0.0 Rel Date: 13-Aug-2018 Page 1 of 1

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000SS

Sample Description:

Sample Code: Fmp22124 54514

Lucideon Sample Number: UK222685-17039

Lucideon Report Number: UK222685-17039/MFEP

Issue Number:

Date Logged:

30-Jun-2022

Order Number:

402874

12-Jul-2022

to 26-Jul-2022

Date Reported:

26-Jul-2022

Date(s) of Test(s):

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

