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CERTIFICATE OF ANALYSIS

Date:

31 August 2022

Product Name	CLEARKL	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202			
Batch Number	FMP22213	55056		
Production Date	01/08/2022			
Expiration Date	EXP 01/08/2025			

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	7.8	

On behalf of Diversey site Quality Manger	Name:	Justyna Staron urszula Haraburda
	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 2173-30420A

Product Code Lot Number Quantity UOM
TEGO 2000SC DV4724 55056 149 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 55056, SAMPLE BOX 5 Case

Validation Reference Number: 4724

Processing Run Start Date: 16-Aug-2022 7:48 AM
Processing Run End Date: 16-Aug-2022 5:49 PM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 29.7 Reference Dose Range (kGy): 29.4 - 40.5 Calculated Max Dose (kGy): 39.4

PO Number: 403202

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

Signature Manifest

Reviewed and E-Signed By: Nidhi Patel (Quality Engineer)

Date/Time E-Signed: 17-Aug-2022 12:03 PM

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: 120042

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 LA1 4XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000 SC

Sample Description:

Sample Code: Fmp22213 55056

Lucideon Sample Number: UK223488-22664

Lucideon Report Number: UK223488-22664/MFEP

Issue Number:

Date Logged:

31-Aug-2022

Order Number:

403305

Date Reported:

10-Oct-2022

Date(s) of Test(s):

22-Sep-2022 to 10-Oct-2022

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 Natalie Boot

Senior Business Support Administrator