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CERTIFICATE OF ANALYSIS

Date:

19 October 2022

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP22269	55370	
Production Date	26/09/2022		
Expiration Date	EXP 26/03/2024		

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
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:	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 2173-31522A

Product CodeLot NumberQuantityUOMTEGO 2000SS BLK1 DV476755370115Case

Validation Reference Number: 4767

TEGO 2000SS BLK1 DV4767 55370, 3 x samples 3 Case

Validation Reference Number: 4767

Processing Run Start Date: 06-Oct-2022 8:37 AM
Processing Run End Date: 06-Oct-2022 5:44 PM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 26.5

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 38.7

PO Number: 403515

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 07-Oct-2022 2:25 AM

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: 124230

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

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000SS

Sample Description:

Sample Code: Fmp22269 55370

Lucideon Sample Number: UK224069-26474

Lucideon Report Number: UK224069-26474/MFEP

Issue Number:

1

Date Logged:

18-Oct-2022

Order Number:

403682

Date Reported:

08-Nov-2022

Date(s) of Test(s):

20-Oct-2022 to 03-Nov-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

Robin Williams

Microbiology Laboratory Supervisor