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CERTIFICATE OF ANALYSIS

Date:

17 November 2020

Product Name	CLEARKLENS TEGO 2000SS VH25S			
Product Code	7516427			
Batch Number	FMP20308	50348		
Production Date	03/11/2020	00010		
Expiration Date	EXP 03/05/2022			

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	Limits Lower - Upper		Results	
Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid	
DM001	6.2	8.2	7.5	
DM004	0.980	1.020	0.997	
	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

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COA Template	Version: 02	Date of issuing: November 24th
		Date of issuing . November 2411

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-14918A

Product Code Lot Number Quantity UOM

TEGO 2000SS BLK1 DV4767 WO50348, INC 3 SMPLS 63 Case

Validation Reference Number: 4767

Processing Run Start Date: 10-Nov-20 05:02 PM

Processing Run End Date: 11-Nov-20 12:46 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 28.1

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 41.6

PO Number: 36752

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: 64597

Last Revised in Rel 2.0.0.0 Rel Date: 08/13/2018

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: Fmp20308 50348

Lucideon Sample Number: UK204707-33227

Lucideon Report Number: UK204707-33227/MFEP

Issue Number:

Date Logged:

18-Nov-2020

Order Number:

PO 36848

Date Reported:

11-Dec-2020

Date(s) of Test(s):

26-Nov-2020 to 10-Dec-2020

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 Assistant

Lucideon Limited

Stoke-on-Trent