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CERTIFICATE OF ANALYSIS

Date: 18 January 2021

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP20352	51350	
Production Date	17/12/2020		
Expiration Date	EXP 17/06/2022		

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	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
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-16188A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SS BLK1 DV4767	WO51350, 3 SMPLS	63	Case
Validation Reference Number: 4767			

Processing Run Start Date: 12-Jan-21 02:04 AM

Processing Run End Date: 12-Jan-21 10:36 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	28.8
Reference Dose Range (kGy):	31.5 - 39.7	Calculated Max Dose (kGy):	41.8

PO Number: 37138

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

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Tego 2000 SS

Sample Description: Sample Code: Fmp20352 51350

Lucideon Sample Number: UK21240-1629

Lucideon Report Number: UK21240-1629/MFEP

Issue Number: 1

Date Logged: 19-Jan-2021

Order Number: PO 37221

Date Reported: 17-Feb-2021

Date(s) of Test(s): 02-Feb-2021 to 16-Feb-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

Nc Boot 17-Feb-21

Mrs Natalie Boot

Business Support Administrator

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