

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date 10 February 2023

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP23019	56139	
Production Date	19/01/2023		
Expiration Date	EXP 19/07/2024		

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	7.5
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 Tamplata	Varsian : 04	Date of issuina: March 11th 2019
ICOA lemplate	Version: 04	Date of issuina : March 11th 2019

STERIS: Gamma Certificate Of Processing

Prepared for:

FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID

2173-34521A

Product Code

Lot Number

Quantity

UOM

TEGO 2000SS BLK1 DV4767

56139 FMP23019

123 Case

Validation Reference Number:

4767

4767

TEGO 2000SS BLK1 DV4767

56139 FMP23019 3 x sample boxes

Case

Validation Reference Number:

Processing Run Start Date: 01-Feb-2023 2:26 PM

Processing Run End Date: 01-Feb-2023 10:09 PM

Specified Dose Range (kGy):

25.0 - 45.0

Calculated Min Dose (kGy):

27.6

Reference Dose Range (kGv):

31.5 - 39.7

Calculated Max Dose (kGy):

Rel Date: 13-Aug-2018

39.9

PO Number: 404384

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 02-Feb-2023 8:38 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: 13438

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: Fmp23019 56139

Lucideon Sample Number: UK23481-3293

Lucideon Report Number: UK23481-3293/MFEP

Issue Number:

Date Logged:

09-Feb-2023

Order Number:

404538

Date Reported:

06-Mar-2023

Date(s) of Test(s):

15-Feb-2023 to 05-Mar-2023

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

Lucideon Limited

Stoke-on-Trent