

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 27 March 2023

Product Name	CLE	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427			
Batch Number	FMP23053	56438		
Production Date	22/02/2023			
Expiration Date	EXP 22/08/2024			

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	1.0

On behalf of Diversey site	Name:	Angelíka Partynska Natlía Traíchel
Quality Manger	Position	Quality Control Inspector

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COA Template	Version : 04	Date of issuing: March 11th 2019
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-35489A

Product CodeLot NumberQuantityUOMTEGO 2000SS BLK1 DV476756438124 Case

Validation Reference Number: 4767

TEGO 2000SS BLK1 DV4767 56438 3 X SAMPLES 3 Case

Validation Reference Number: 4767

Processing Run Start Date: 07-Mar-2023 6:58 PM

Processing Run End Date: 08-Mar-2023 2:48 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 28.6

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 42.1

PO Number: 404700

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 08-Mar-2023 7:01 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: 137446

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

FAO: Mrs.Olga Kirchner

Report of Tests on:

Tego 2000SS

Sample Description:

Sample Code: Fmp23053 56438

Lucideon Sample Number: UK231116-7631

Lucideon Report Number: UK231116-7631/MFEP

Issue Number:

Date Logged:

28-Mar-2023

Order Number:

404925

Date Reported:

20-Apr-2023

Date(s) of Test(s):

30-Mar-2023 to 13-Apr-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

NOBORT 20APT 23

Mrs Natalie Boot

Senior Business Support Administrator

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