

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date: 10 January 2023

Product Name		CLEARKLENS TEGO 2000SC VH25	
Product Code	101103467		
Batch Number	FMP22328	55634	
<b>Production Date</b>	24/11/2022		
Expiration Date	EXP 24/11/202	5	

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
Specific Gravity (20°C)	DM004	0.993	1.003	1.000
pH (neat solution)	DM001	7.5	8.5	7.9

On behalf of Diversey site	Name:	Urszula Haraburda Edyta Rodrígues	
Quality Manger	Position	Quality Control Inspector	

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		COA Template	Version: 02	Date of issuing: November 24th 2017
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# **STERIS: Gamma Certificate Of Processing**

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-33823A

Product Code Lot Number Quantity UOM
TEGO 2000SC DV4724 FMP22328 - 55634 94 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 FMP22328 - 55634, SAMPLE BOX 1 Case

Validation Reference Number: 4724

Processing Run Start Date: 29-Dec-2022 8:27 PM

Processing Run End Date: 30-Dec-2022 3:49 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 29.1

Reference Dose Range (kGy): 29.4 - 40.5 Calculated Max Dose (kGy): 38.8

PO Number: 404209

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

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 30-Dec-2022 4:49 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: 131675

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 LA1 4XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000SC

**Sample Description:** 

Sample Code: Fmp22328 55634

Lucideon Sample Number: UK23110-812

Lucideon Report Number: UK23110-812/MFEP

Issue Number:

1

Date Logged:

11-Jan-2023

Order Number:

404270

Date Reported:

27-Jan-2023

Date(s) of Test(s):

12-Jan-2023 to 26-Jan-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