

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 02 May 2023

Product Name	CLEAI	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202			
Batch Number	FMP23103	56820		
<b>Production Date</b>	13/04/2023			
<b>Expiration Date</b>	EXP 13/04/2026			

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	0.999
pH (neat solution)	DM001	7.5	8.5	8.3

On behalf of Diversey site	Name:	Justyna Staron Angelika Partynska	
Quality Manger	Position	Quality Control Inspector	

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## **STERIS: Gamma Certificate Of Processing**

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-36669A

Product Code Lot Number Quantity UOM
TEGO 2000SC DV4724 56820 184 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 56820, 1 X SAMPLE BOX 1 Case

Validation Reference Number: 4724

Processing Run Start Date: 25-Apr-2023 11:22 PM

Processing Run End Date: 26-Apr-2023 7:34 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 31.2

Reference Dose Range (kGy): 29.4 - 40.5 Calculated Max Dose (kGy): 41.4

PO Number: 405069

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

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 26-Apr-2023 2:23 PM

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: 141621

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 2000SC

Sample Description:

Sample Code: Fmp23103 56820

Lucideon Sample Number: UK231596-11047

Lucideon Report Number: UK231596-11047/MFEP

Issue Number:

1

**Date Logged:** 

03-May-2023

Order Number:

405172

**Date Reported:** 

24-May-2023

Date(s) of Test(s):

05-May-2023 to 23-May-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** 

DocuSigned by:

Natalie Boot

Signer Name: Natalie Boot Signing Reason: I have reviewed this document Signing Time: 24 May 2023 | 10:11 BST

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Mrs Natalie Boot

Senior Business Support Administrator

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