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### **CERTIFICATE OF ANALYSIS**

Date:

13 May 2021

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP21111	51722	
Production Date	21/04/2021		
Expiration Date	EXP 21/04/2024		

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
Specific Gravity (20°C)	DM004	0.993	1.003	0.999
pH (neat solution)	DM001	7.5	8.5	7.9

On behalf of Diversey site  Quality Manger	Name:	Justyna Staron urszula Haraburda
	Position	Quality Control Inspector

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COA Template Version: 02 Date of issuing: November 24th 2017

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

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-18960A

TEGO 2000SC DV4724 WO51722 60 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 WO51722, INC 1 SMPL 50 Case

Validation Reference Number: 4724

Processing Run Start Date: 03-May-21 07:44 PM

Processing Run End Date: 04-May-21 02:53 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): 39.3

PO Number: 37944

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

Document ID: 77786

Last Revised in Rel 2.0.0.0 Rel Date: 08/13/2018

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000 SC

Sample Description:

Sample Code: Fmp21111 51722

Lucideon Sample Number: UK212095-14645

Lucideon Report Number: UK212095-14645/MFEP

Issue Number:

Date Logged:

13-May-2021

Order Number:

PO 38044

**Date Reported:** 

11-Jun-2021

Date(s) of Test(s):

20-May-2021 to 03-Jun-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** 

15-11-JUN-21

Mrs Natalie Boot

**Business Support Administrator**