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### **CERTIFICATE OF ANALYSIS**

Date:

06 May 2021

Product Name	CLEARKLENS TEGO 2000SS VH25S			
Product Code	7516427			
Batch Number	FMP21102	51716		
Production Date	12/04/2021			
Expiration Date	EXP 12/10/2022			

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	7.6	
Specific Gravity (20°C)	DM004	0.980	1.020	1.001	

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: 2173-18816A

<u>Product Code</u> <u>Lot Number</u> <u>Quantity</u> <u>UOM</u>

TEGO 2000SS BLK1 DV4767 WO51716, INC 3 SAMPLES 19 Case

Validation Reference Number: 4767

Processing Run Start Date: 26-Apr-21 01:40 AM

Processing Run End Date: 26-Apr-21 09:03 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 26.4

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 39.4

PO Number: 37882

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: 77189

Rel Date: 08/13/2018

Last Revised in Rel 2.0.0.0

# 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 2000SS

Sample Description:

Sample Code: Fmp21102 51716

Lucideon Sample Number: UK212008-13938

Lucideon Report Number: UK212008-13938/MFEP

Issue Number:

1

Date Logged:

07-May-2021

**Order Number:** 

PO 37992

**Date Reported:** 

27-May-2021

Date(s) of Test(s):

11-May-2021 to 25-May-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** 

Mrs Andrea Saunders

**Business Support Administrator**