

Diversey Europe Operations EV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date:

06 May 2021

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP21105	51900	
Production Date	15/04/2021		
Expiration Date	EXP 15/10/2022		

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	Lim Lower	its - Upper	Results
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	1.001

On behalf of Diversey site	Name:	Justyna Staron	Urszula Haraburda
Quality Manger	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: 2173-18770A

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

TEGO 2000SS BLK1 DV4767 WO51900 54 Case

Validation Reference Number: 4767

TEGO 2000SS BLK1 DV4767 WO51900, INC 3 SAMPLES 72 Case

Validation Reference Number: 4767

Processing Run Start Date: 26-Apr-21 01:02 AM

Processing Run End Date: 26-Apr-21 08:57 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 27.5

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 43.3

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: 77191

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 LA1 4XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000SS

Sample Description:

Sample Code: Fmp21105 51900

Lucideon Sample Number: UK212008-13939

Lucideon Report Number: UK212008-13939/MFEP

Issue Number:

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** 

**Business Support Administrator**