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## CERTIFICATE OF ANALYSIS

Date: 14 September 2021

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP21231	52593	
Production Date	19/08/2021		
Expiration Date	EXP 19/02/2023		

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	7.2
Specific Gravity (20°C)	DM004	0.980	1.020	0.999

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda    Angelika Partynska
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

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: 2173-21982A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SS BLK1 DV4767	52593 FMP21231	124	Case
Validation Reference Number: 4767			
TEGO 2000SS BLK1 DV4767	52593 FMP21231, 3 x samples	3	Case
Validation Reference Number: 4767			

Processing Run Start Date: 29-Aug-2021 7:19 AM

Processing Run End Date: 29-Aug-2021 4:06 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	29.2
Reference Dose Range (kGy):	31.5 - 39.7	Calculated Max Dose (kGy):	42.4

PO Number: 400685

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

**Gamma Process Run Approval authorized by STERIS**

Date/Time E-Signed: 29-Aug-2021 8:21 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

# PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Mrs.Olga Kirchner

**Report of Tests on:** Tego 2000 SS

**Sample Description:** Sample Code: Fmp21231 52593

**Lucideon Sample Number:** UK213927-26501

**Lucideon Report Number:** UK213927-26501/MFEP **Issue Number:** 1

**Date Logged:** 15-Sep-2021 **Order Number:** 400844

**Date Reported:** 06-Oct-2021 **Date(s) of Test(s):** 18-Sep-2021 to 02-Oct-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**

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