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## CERTIFICATE OF ANALYSIS

Date: 07 December 2020

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP20322	50920	
Production Date	17/11/2020		
Expiration Date	EXP 17/05/2022		

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	7.5
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
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# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-15434A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SS BLK1 DV4767	WO50920, INC 3 SMPLS	62	Case

Validation Reference Number: 4767

Processing Run Start Date: 30-Nov-20 03:36 AM

Processing Run End Date: 30-Nov-20 11:04 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	30.0
Reference Dose Range (kGy):	31.5 - 39.7	Calculated Max Dose (kGy):	43.1

PO Number: 36894

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

## Signature Manifest

Reviewed and E-Signed By: **Nelia Dias (Quality Engineer)**

Date/Time E-Signed: 2020-12-01 07:57 AM

Document Content Revision: 1

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: Fmp20322 50920

**Lucideon Sample Number:** UK205021-34978

**Lucideon Report Number:** UK205021-34978/MFEP **Issue Number:** 1

**Date Logged:** 08-Dec-2020 **Order Number:** PO 36975

**Date Reported:** 17-Feb-2021 **Date(s) of Test(s):** 28-Jan-2021 to 16-Feb-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**

NCBat 17-Feb-21

Mrs Natalie Boot

**Business Support Administrator**

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