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## CERTIFICATE OF ANALYSIS

Date: 06 November 2023

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	101107171		
Batch Number	FMP23284	59074	
Production Date	11/10/2023		
Expiration Date	EXP 11/10/2026		

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	0.996
pH (neat solution)	DM001	7.5	8.5	8.2

On behalf of Diversey site Quality Manger	Name:	Justyna Staron      Angelika Pietraszko
	Position	Quality Control Inspector

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

COA Template	Version : 04	Date of issuing : March 11th 2019
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# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-41555A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	59074	44	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	59074, 2 X SAMPLES	2	Case
Validation Reference Number: 4724			

Processing Run Start Date: 25-Oct-2023 7:11 AM

Processing Run End Date: 25-Oct-2023 3:07 PM

<b>Specified Dose Range (kGy):</b>	<b>25.0 - 45.0</b>	<b>Calculated Min Dose (kGy):</b>	<b>25.6</b>
<b>Reference Dose Range (kGy):</b>	<b>29.4 - 40.5</b>	<b>Calculated Max Dose (kGy):</b>	<b>34.5</b>

All dosimeters measured within the required reference dose range to meet Customer dose specification.

PO Number: 405018

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

**Gamma Process Run Approval authorized by STERIS**

Date/Time: 25-Oct-2023 5:46 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



## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Mrs. Olga Kirchner

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

**Sample Description:** Sample Code: Fmp23284 59074

**Lucideon Sample Number:** UK234055-30666

**Lucideon Report Number:** UK234055-30666/MFEP **Issue Number:** 1

**Date Logged:** 07-Nov-2023 **Order Number:** 406739

**Date Reported:** 01-Dec-2023 **Date(s) of Test(s):** 13-Nov-2023 to 01-Dec-2023

### 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**

DocuSigned by:

*Natalie Boot*

Signer Name: Natalie Boot  
Signing Reason: I have reviewed this document  
Signing Time: 01 December 2023 | 15:27 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator**

Page 1 of 1

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