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## CERTIFICATE OF ANALYSIS

Date: 02 May 2023

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	101103467		
Batch Number	FMP23095	56744	
Production Date	05/04/2023		
Expiration Date	EXP 05/04/2026		

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	0.997
pH (neat solution)	DM001	7.5	8.5	8.3

On behalf of Diversey site Quality Manger	Name:	Justyna Staron      Angelika Partynska
	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 2173-36508A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	56744	94	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	56744, SAMPLE BOX	1	Case
Validation Reference Number: 4724			

Processing Run Start Date: 17-Apr-2023 2:57 AM

Processing Run End Date: 19-Apr-2023 2:56 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	31.8
Reference Dose Range (kGy):	29.4 - 40.5	Calculated Max Dose (kGy):	44.0

PO Number: 405018

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

## Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 19-Apr-2023 7:15 AM

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: Fmp23095 56744

**Lucideon Sample Number:** UK231596-11046

**Lucideon Report Number:** UK231596-11046/MFEP **Issue Number:** 1

**Date Logged:** 03-May-2023 **Order Number:** 405172

**Date Reported:** 24-May-2023 **Date(s) of Test(s):** 05-May-2023 to 23-May-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: 24 May 2023 | 10:11 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator**

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