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## CERTIFICATE OF ANALYSIS

Date: 25 June 2020

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100961418		
Batch Number	FMP20155	50103	
Production Date	03/06/2020		
Expiration Date	EXP 03/06/2023		

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
Specific Gravity (20°C)	DM004	0.993	1.003	0.998
pH (neat solution)	DM001	7.5	8.5	8.1

On behalf of Diversey site Quality Manger	Name:	Angelika Partynska    Urszula Haraburda
	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: 2173-11259A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	FMP20155 50103	89	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	FMP20155 50103, 1 X SAMPLE BOX	1	Case
Validation Reference Number: 4724			

Processing Run Start Date: 15-Jun-20 11:24 PM

Processing Run End Date: 16-Jun-20 06:29 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	28.1
Reference Dose Range (kGy):	29.4- 40.5	Calculated Max Dose (kGy):	38.3

PO Number: PO35652

**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

# 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 2000 SC

**Sample Description:** Sample Code: Fmp20155 50103

**Lucideon Sample Number:** UK202591-18865

**Lucideon Report Number:** UK202591-18865/MFEP **Issue Number:** 1

**Date Logged:** 24-Jun-2020 **Order Number:** PO 35764

**Date Reported:** 15-Jul-2020 **Date(s) of Test(s):** 02-Jul-2020 to 15-Jul-2020

### 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**



15 JUL 20

Mrs Andrea Saunders

**Business Support Assistant**

Page 1 of 1

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