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## CERTIFICATE OF ANALYSIS

Date: 23/08/19

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	100961418
Batch Number	FMP 19165 47429
Production Date	14/06/2019
Expiration Date	EXP 14/06/2022

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
Specific Gravity (20°C)	DM004	0.993	1.003	1.002
pH (neat solution)	DM001	7.5	8.5	8.1

On behalf of Diversey site Quality Manager	Name :	Ratysko
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template

Version : 02

Date of Issuing : November 24<sup>th</sup> 2017

# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4449A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	FMP19165	97	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	FMP19165 1 X SAMPLE	1	Case
Validation Reference Number: 4724			

Processing Run Start Date: 03-Aug-19 11:18 PM

Processing Run End Date: 04-Aug-19 06:36 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	28.4
Reference Dose Range (kGy):	29.4- 40.5	Calculated Max Dose (kGy):	39.6

PO Number: PO33538

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

## Other Information

Please note the Lot Number reference should be FMP19135 47429

## Signature Manifest

Reviewed and E-Signed By: **Mark Morse (QA Officer)**

Date/Time E-Signed: 2019-08-05 11:54 AM

Document Content Revision: 2

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: Alison Siddle

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

**Sample Description:** Sample Code: FMP19165 47429

**Lucideon Sample Number:** (194680)-36055

**Lucideon Report Number:** (194680)-36055/MFEP

**Issue Number:** 1

**Date Logged:** 21-Aug-2019

**Order Number:** PO33752

**Date Reported:** 29-Nov-2019

**Date(s) of Test(s):** 14-Nov-2019 to 28-Nov-2019

### 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**

Nat Boot 29 Nov 19

Mrs Natalie Boot

**Senior Business Support Assistant**

Page 1 of 1

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