

Diversey Europe Operations BV Magrasenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427 www.Diversey.com

# **CERTIFICATE OF ANALYSIS**

Date: 11.11.2019

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100961418		
Batch Number	FMP 19277 48170		
Production Date	04/10/2019		
Expiration Date	FXP (04 1 1012022		

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 Lower - U	Results
Appearance	Visual	Clear Slightly You	ellow Clear Sciphtly
Specific Gravity (20°C)	DM004	0.993 1	.003
pH (neat solution)	DM001		8.5 7.8

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

This document being issued electronically does not bear a signature

COA Template Version : 02	Date of issuing: November 24th 2017
---------------------------	-------------------------------------

# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-5756A

**Product Code Lot Number** Quantity **UOM TEGO 2000SC DV4724** FMP19277, 48470 98 Case

**Validation Reference Number:** 4724

Processing Run Start Date: 22-Oct-19 12:27 PM Processing Run End Date: 22-Oct-19 07:33 PM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 28.8

38.0 Reference Dose Range (kGy): 29.4-40.5 Calculated Max Dose (kGy):

### 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

Document ID: 30909

Last Revised in Rel 2.0.0.0

Page 1 of 1

Rel Date: 08/13/2018

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000 SC

Sample Description:

Sample Code: Fmp19277 48470

Lucideon Sample Number: (196202)-47210

Lucideon Report Number: (196202)-47210/MFEP

Issue Number:

Date Logged:

12-Nov-2019

**Order Number:** 

34274

**Date Reported:** 

03-Dec-2019

Date(s) of Test(s):

16-Nov-2019 to 30-Nov-2019

**Sterility Testing** Membrane Filtration EP

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

**End of Test Report** 

NOBOOK 03-Dec-19

Mrs Natalie Boot

**Senior Business Support Assistant**