STERIS: Gamma Certificate Of Processing

Prepared for: **FLEXIBLE MEDICAL PACKAGING LTD (8245)**

Gamma Process Run ID **2173-29478A**

Product Code	Lot Number	Quantity	UOM
TEGO 2000SC DV4724	**54470**	**120**	**Case**
Validation Reference Number: 4724			
TEGO 2000SC DV4724	**54470, SAMPLE BOX**	**1**	**Case**
Validation Reference Number: 4724			

Processing Run Start Date: 10-Jul-2022 11:25 PM

Processing Run End Date: 11-Jul-2022 7:30 AM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**29.3**
Reference Dose Range (kGy):	**29.4 - 40.5**	**Calculated Max Dose (kGy):**	**38.8**

PO Number: 402719

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

Signature Manifest

Reviewed and E-Signed By: **Nelia Dias (Quality Engineer)**

Date/Time E-Signed: 12-Jul-2022 7:57 AM

Document Content Revision: 1

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: Mrs.Olga Kirchner

Report of Tests on:	Tego 2000SC		
Sample Description:	Sample Code: Fmp22133 54470		
Lucideon Sample Number:	UK222981-19125		
Lucideon Report Number:	UK222981-19125/MFEP	**Issue Number:**	1
Date Logged:	22-Jul-2022	**Order Number:**	403077
Date Reported:	15-Aug-2022	**Date(s) of Test(s):**	26-Jul-2022 **to** 13-Aug-2022

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

NBoot 15-Aug-22

Mrs Natalie Boot
Senior Business Support Administrator

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CERTIFICATE OF ANALYSIS

Date: 25 July 2022

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP22133 54470
Production Date	13/05/2022
Expiration Date	EXP 13/05/2025

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	- Upper	Results
Appearance	Visual	Clear Slightly Yellow Liquid		Clear Slightly Yellow Liquid
Specific Gravity (20°C)	DM004	0.993	1.003	0.999
pH (neat solution)	DM001	7.5	8.5	8.0

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

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