

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 13 February 2023

Product Name		CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202			
Batch Number	FMP23026	56764		
Production Date	26/01/2023			
Expiration Date	EXP 26/01/2026)		

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	Name:	Justyna Staron	Urszula Haraburda
Quality Manger	Position	Quality Control Inspector	

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COA Template	Version: 04	Date of issuing: March 11th 2019

STERIS: Gamma Certificate Of Processing

Prepared for:

FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID

2173-34754A

Product Code

Lot Number

Quantity

MOU

TEGO 2000SC DV4724

56764 - FMP23026

149 Case

Validation Reference Number:

4724

TEGO 2000SC DV4724

56764 - FMP23026, SAMPLE BOX

Case

Validation Reference Number:

Processing Run Start Date: 08-Feb-2023 6:17 PM

Processing Run End Date: 09-Feb-2023 2:04 AM

Specified Dose Range (kGy):

25.0 - 45.0

Calculated Min Dose (kGy):

29.0

Reference Dose Range (kGy):

29.4 - 40.5

Calculated Max Dose (kGy):

Rel Date: 13-Aug-2018

39.3

PO Number: 404465

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 09-Feb-2023 5:09 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

Document ID: 13508

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: Fmp23026 56764

Lucideon Sample Number: UK23545-3782

Lucideon Report Number: UK23545-3782/MFEP

Issue Number:

Date Logged:

14-Feb-2023

Order Number:

404570

Date Reported:

14-Mar-2023

Date(s) of Test(s):

21-Feb-2023 to 10-Mar-2023

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 Refer to Deviation Report DEV 8781.

End of Test Report

NOBOOK ILMOT 23.

Mrs Natalie Boot

Senior Business Support Administrator