

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 20 February 2023

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP23011 56318		
Production Date	11/01/2023		
Expiration Date	EXP 11/01/2026		

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	0.998
pH (neat solution)	DM001	7.5	8.5	8.4

On behalf of Diversey site	Name:	Justyna Staron	Ilona Goralska
Quality Manger	Position	Quality (Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 04	Date of issuing: March 11th 2019
CONTINUE	V C/3/0// . O /	Bare or issuing . March Tim 2017

STERIS: Gamma Certificate Of Processing

Prepared for:

FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID

2173-34322A

Product Code

Lot Number

Quantity

UOM

TEGO 2000SC DV4724

56318 - FMP23011

150 Case

Validation Reference Number:

4724

TEGO 2000SC DV4724

56318 - FMP23011, SAMPLE BOX

Case

Validation Reference Number:

4724

Processing Run Start Date: 24-Jan-2023 12:02 AM

Processing Run End Date: 24-Jan-2023 7:24 AM

Specified Dose Range (kGy):

25.0 - 45.0

Calculated Min Dose (kGy):

28.8

Reference Dose Range (kGy):

29.4 - 40.5

Calculated Max Dose (kGy):

38.1

PO Number: 404331

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 24-Jan-2023 8:27 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: 13364

Last Revised in Rel 2.0.0.0

Rel Date: 13-Aug-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 2000SC

Sample Description:

Sample Code: Fmp23011 56318

Lucideon Sample Number: UK23639-4286

Lucideon Report Number: UK23639-4286/MFEP

Issue Number:

Date Logged:

21-Feb-2023

Order Number:

404616

Date Reported:

Date(s) of Test(s):

01-Mar-2023 to 19-Mar-2023

21-Mar-2023

Sterility Testing

Membrane Filtration EP

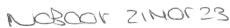
Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report



Lucideon Limited