

Diversey Europe Operations BV Maarssenbroeksedlik 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 03 09 2019

Product Name	CLEARKLENS TEGO 2000SC VH25			
Product Code	100868202			
Batch Number	EHP 19208 17381			
Production Date	2710712019			
Expiration Date	EXP 27/07/2022			

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 Lower - Upper Clear Slightly Yellow Liquid		Results Clear Stightle Yellow Lightle	
Appearance	Visual				
Specific Gravity (20°C)	DM004	0.993	1.003	0.998	
pH (neat solution)	DM001	7.5	8.5	7.7	

Quality Manager	Position	Quality Control Inspector
On behalf of Diversey site	Name:	Partyristo A Bours

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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: 2173-4660A

 Product Code
 Lot Number
 Quantity
 UOM

 TEGO 2000SC DV4724
 FMP19208 47381
 98
 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 FMP19208 47381, INC 1 SMPL 1 Case

Validation Reference Number: 4724

Processing Run Start Date: 23-Aug-19 09:50 AM
Processing Run End Date: 23-Aug-19 10:40 PM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 27.4

Reference Dose Range (kGy): 29.4- 40.5 Calculated Max Dose (kGy): 36.6

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: 27301

Rel Date: 08/13/2018

Last Revised in Rel 2.0.0.0

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO:

Alison Siddle

Report of Tests on:

Tego 2000SC

Sample Description:

FMP19208 47381

Lucideon Sample Number: (194869)-37742

Lucideon Report Number: (194869)-37742/MFEP

Issue Number:

Date Logged:

02-Sep-2019

Order Number:

PO33824

Date Reported:

14-Nov-2019

Date(s) of Test(s):

25-Oct-2019 to 12-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

Mrs Andrea Saunders

Business Support Assistant

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Lucideon Limited

Stoke-on-Trent