

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 May 2021

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP21117	51976	
Production Date	27/04/2021		
Expiration Date	EXP 27/04/2024		

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
Specific Gravity (20°C)	DM004	0.993	1.003	0.999
pH (neat solution)	DM001	7.5	8.5	7.8

On behalf of Diversey site	Name:	Justyna Staron	urszula Haraburda
Quality Manger	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: 2173-18959A

Product Code Lot Number Quantity UOM

TEGO 2000SC DV4724 WO51976, INC 1 SMPL 30 Case

Validation Reference Number: 4724

Processing Run Start Date: 03-May-21 07:34 PM
Processing Run End Date: 04-May-21 02:40 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): 38.5

PO Number: 37944

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

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: 77788

Last Revised in Rel 2.0.0.0 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: Fmp21117 51976

Lucideon Sample Number: UK212095-14646

Lucideon Report Number: UK212095-14646/MFEP

Issue Number:

1

Date Logged:

13-May-2021

Order Number:

PO 38044

Date Reported:

11-Jun-2021

Date(s) of Test(s):

20-May-2021 to 03-Jun-2021

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

15-nu-21

Mrs Natalie Boot

Business Support Administrator

Page 1 of 1

Lucideon Limited

Staffordshire ST4 7LQ

Stoke-on-Trent