

versey Europe Operations BV saresenbroeksedijk 2 42 DN Utrecht se Netherlands

sl. +31 (0)30 247 6427 sw.Diversey.com

CERTIFICATE OF ANALYSIS

Date:

17 November 2020

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP20304	50349	
Production Date	30/10/2020	00012	
Expiration Date	EXP 30/10/2023		

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	1.001
pH (neat solution)	DM001	7.5	8.5	7.8

On behalf of Diversey site Quality Manger	Name:	Angelika Partynska Justyna Staron
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template Version : 02 Date of issuing : November 24th

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-14915A

Product Code Lot Number Quantity UOM

TEGO 2000SC DV4724 WO50349 50 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 WO50349, INC 1 SMPL 47 Case

Validation Reference Number: 4724

Processing Run Start Date: 10-Nov-20 07:18 PM

Processing Run End Date: 11-Nov-20 03:15 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 30.7

Reference Dose Range (kGy): 29.4 - 40.5 Calculated Max Dose (kGy): 40.8

PO Number: 36752

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: 64601

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 2000SC

Sample Description:

Sample Code: Fmp20304 50349

Lucideon Sample Number: UK204707-33225

Lucideon Report Number: UK204707-33225/MFEP

Issue Number:

Date Logged:

18-Nov-2020

Order Number:

PO 36848

Date Reported:

11-Dec-2020

Date(s) of Test(s):

26-Nov-2020 to 10-Dec-2020

Sterility Testing

Membrane Filtration EP

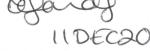
Test Results:

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

Lucideon Limited

Stoke-on-Trent