

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 03 April 2023

Product Name	CI	CLEARKLENS TEGO 2000SC VH25		
Product Code	101103467			
Batch Number	FMP23075	56743		
Production Date	16/03/2023			
Expiration Date	EXP 16/03/2026			

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	1.001
pH (neat solution)	DM001	7.5	8.5	7.9

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

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-36060A

Product Code Lot Number Quantity UOM
TEGO 2000SC DV4724 56743 103 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 56743, Sample Box 1 Case

Validation Reference Number: 4724

Processing Run Start Date: 28-Mar-2023 2:01 PM

Processing Run End Date: 29-Mar-2023 12:57 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 30.1

Reference Dose Range (kGy): 29.4 - 40.5 Calculated Max Dose (kGy): 40.2

PO Number: 404881

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 29-Mar-2023 7:09 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: 139214

N/A Last Revised in Rel 2.0.0.0 Rel Date: 13-Aug-2018 Page 1 of 1

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: Fmp23075 56743

Lucideon Sample Number: UK231224-8217

Lucideon Report Number: UK231224-8217/MFEP

Issue Number:

Date Logged:

04-Apr-2023

Order Number:

404949

Date Reported: 21-Apr-2023

Date(s) of Test(s):

06-Apr-2023 to 20-Apr-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

NOBOOK 21APT 23

Mrs Natalie Boot

Senior Business Support Administrator

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested.