

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 09.10.2019

Product Name	CLEARKLENS TEGO 2000SS VH25S
Product Code	7516427
Batch Number	FMP 19246, 48035
Production Date	0310912019
Expiration Date	EXP 03 031 2021

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	
Appearance	Visual			clear slightly	
pH (neat solution)	DM001	6.2	8.2	7.7	
Specific Gravity (20°C)	DM004	0.990	1.010	0.998	

On behalf of Diversey site Quality Manager	Name :	Navaberda Partyrist
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version: 02	Date of issuing: November 24 2017	
- CONTROLLE	74.01077.02	Date of 1990mil . Hoveliber 27 2027	

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-5274A

Product CodeLot NumberQuantityUOMTEGO 2000SS BLK1 DV4767FMP19246 4803560 Case

Validation Reference Number: 4767

TEGO 2000SS BLK1 DV4767 FMP19246 48035, INC 4 SMPLS 4 Case

Validation Reference Number: 4767

Processing Run Start Date: 24-Sep-19 02:08 AM
Processing Run End Date: 24-Sep-19 09:46 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 29.0

Reference Dose Range (kGy): 31.5-39.7 Calculated Max Dose (kGy): 42.1

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: 29211

Last Revised in Rel 2.0.0.0

Rel Date: 08/13/2018 Page 1 of 1

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000SS

Sample Description:

Sample Code: Fmp19246 48035

Lucideon Sample Number: (195667)-43298

Lucideon Report Number: (195667)-43298/MFEP

Issue Number:

1

Date Logged:

11-Oct-2019

Order Number:

34061

Date Reported:

03-Jan-2020

Date(s) of Test(s):

20-Dec-2019 to 03-Jan-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

08-101-ED 10080

Mrs Natalie Boot

Senior Business Support Assistant

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be