

versey Europe Operations BV sarssenbroeksedijk 2 42 DN Utrecht se Netherlands

il. +31 (0)30 247 6427 ww.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 17 November 2020

Product Name	CLEARKL	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427			
Batch Number	FMP20303	50311		
Production Date	29/10/2020			
Expiration Date	EXP 29/04/2022			

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		Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	6.2	8.2	7.5
Specific Gravity (20°C)	DM004	0.980	1.020	0.997

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

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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: 2173-14920A

<u>Product Code</u> <u>Lot Number</u> <u>Quantity</u> <u>UOM</u>

TEGO 2000SS BLK1 DV4767 WO50311, INC 3 SMPLS 63 Case

Validation Reference Number: 4767

Processing Run Start Date: 10-Nov-20 05:16 PM

Processing Run End Date: 11-Nov-20 01:05 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 27.8

Reference Dose Range (kGy): 31.5 - 39.7 Calculated Max Dose (kGy): 41.3

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: 64599

Last Revised in Rel 2.0.0.0

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: Fmp20303 50311

Lucideon Sample Number: UK204707-33226

Lucideon Report Number: UK204707-33226/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

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