

Diversey Europe Operations BV Maarssenbroeksedijk 2 3642 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date:

08 April 2021

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP21087	51307	
Production Date	19/03/2021		
Expiration Date	EXP 19/09/2022		

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	7.4	
Specific Gravity (20°C)	DM004	0.980	1.020	0.999	

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda Angelika Partynska
	Position	Quality Control Inspector

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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: 2173-18175A

Product Code	Lot Number		<u>Quantity</u>	UOM	
TEGO 2000SS BLK1 DV4767	WO51307		54	Case	
Validation Reference Number:	4767				
TEGO 2000SS BLK1 DV4767	WO51307, IN	C 4 SMPLS	71	Case	
Validation Reference Number:	4767				
Processing Run Start Date: 29-Mar-21 05:44 PM					
Processing Run End Date: 30-Mar-21 01:49 AM					
Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose	(kGy):	28.1	
Reference Dose Range (kGy):	31.5 - 39.7	Calculated Max Dose	(kGy):	40.8	

PO Number: 37728

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: 75175

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 2000 SS

Sample Description: Sample Code: Fmp21078 51307

20-May-2021

Lucideon Sample Number: UK211538-11116

Lucideon Report Number: UK211538-11116/MFEP

Date Logged: 09-Apr-2021

Date Reported:

Order Number:

Date(s) of Test(s):

Issue Number:

PO 37804

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05-May-2021 to 19-May-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

20 may 21

Mrs Andrea Saunders Business Support Administrator

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