

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date:

02 March 2021

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP21043	51657	
Production Date	12/02/2021		
Expiration Date	EXP 12/02/2024		

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	1.003	
pH (neat solution)	DM001	7.5	8.5	8.4	

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda Ewelína Markíel
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of issuing : November 24th
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-17254A

Product Code	Lot Number	Q	uantity	<u>UOM</u>	
TEGO 2000SC DV4724	WO51657		89	Case	
Validation Reference Number:	4724				
TEGO 2000SC DV4724	WO51657, SA	AMPLE BOX	1	Case	
Validation Reference Number:	4724				
Processing Run Start Date: 23-Feb-21 07:49 AM					
Processing Run End Date: 23-Feb-21 03:55 PM					
Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (k	Gy):	28.5	
Reference Dose Range (kGy):	29.4 - 40.5	Calculated Max Dose (I	kGy):	38.0	

PO Number: 37468

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: 72427

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 SC

Sample Description: Sample Code: Fmp21043 51657

24-Mar-2021

Lucideon Sample Number: UK21923-6234

Lucideon Report Number: UK21923-6234/MFEP

Date Logged: 03-Mar-2021

Date Reported:

Order Number:

Issue Number:

Date(s) of Test(s): <u>Sterility Testing</u> Membrane Filtration EP PO 37566

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10-Mar-2021 to 24-Mar-2021

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

2BOOK 24-MOR-21

Mrs Natalie Boot Business Support Administrator

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