

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427 www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 20 October 2022

Product Name	CLEARKLENS TEGO 2000SC VH25			
Product Code	101103467			
Batch Number	FMP22228	55551		
Production Date	16/08/2022			
Expiration Date	EXP 16/08/2025			

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	7.9		

On behalf of Diversey site Quality Manger	Name:	Angelika Partynska Urszula Haraburda	
	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 2173-30715A

Product Code	Lot Number	Qua	ntity	<u>UOM</u>	
TEGO 2000SC DV4724	55551		90	Case	
Validation Reference Number:	4724				
TEGO 2000SC DV4724	55551, INC SAMPLE 1		Case		
Validation Reference Number:	4724				
Processing Run Start Date: 30-Aug-2022 5:19 PM					
Processing Run End Date: 31-Aug-202	2 1:29 AM				
Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy	<i>י</i>):	28.6	
Reference Dose Range (kGy):	29.4 - 40.5	Calculated Max Dose (kG	y):	38.0	

PO Number: 403286

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 31-Aug-2022 7:19 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

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging Unit 8 Hightown	3				
White Cross Industrial Estate Lancaster LA1 4XS					
FAO: Mrs.Olga Kirchner					
Report of Tests on:	Tego 2000SC				
Sample Description:	Sample Code: Fmp22228	55551			
Lucideon Sample Number:	UK223867-25066				
Lucideon Report Number:	UK223867-25066/MFEP	Issue Number:	1		
Date Logged:	03-Oct-2022	Order Number:	403540		
Date Reported:		Date(s) of Test(s): erility Testing rane Filtration EP	06-Oct-2022	to	27-Oct-2022
Test Results:					
Result: Pass					
The test results meet the EP/	USP criteria: Yes				

Tests carried out in accordance with cGMP

End of Test Report

280022

Miss Rosie Jones Pharmaceutical Microbiology Manager

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Lucideon Limited Queens Road, Penkhull Stoke-on-Trent Staffordshire ST4 7LQ T +44 (0)1782 764428 enquiries@lucideon.com www.lucideon.com

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