

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date:

15 May 2023

Product Name	CLEA	ARKLENS TEGO 2000SS VH25S
Product Code	7516427	
Batch Number	FMP23117	56878
Production Date	27/04/2023	
Expiration Date	EXP 27/10/2024	

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	Limi Lower	ts - Upper	Results
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	6.2	8.2	7.7
Specific Gravity (20°C)	DM004	0.980	1.020	0.992

On behalf of Diversey site	Name:	Edyta Rodrígues Ewelína Nowaczyk
Quality Manger	Position	Quality Control Inspector

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COA Template Version : 04 Date of issuing : March 11th 2019			
	COA Template	Version : 04	Date of issuing : March 11th 2019

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-37044A

Product Code	Lot Number		<u>Quantity</u>	UOM
TEGO 2000SS BLK1 DV4767	**TO BE PRO DAYS*** 568	DCESSED WITHIN 6 78	126	Case
Validation Reference Number:	4767			
TEGO 2000SS BLK1 DV4767		DCESSED WITHIN 6 78, X 3 SAMPLES	3	Case
Validation Reference Number:	4767			
Processing Run Start Date: 08-May-202	3 8:32 PM			
Processing Run End Date: 09-May-202	3 4:45 AM			
Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Do	ose (kGy):	28.1
Reference Dose Range (kGy):	31.5 - 39.7	Calculated Max D	ose (kGy):	41.9

PO Number: 405191

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 10-May-2023 6:13 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

Document ID: 142724

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 2000SSSample Description:Sample Code: Fmp23117 56878

Lucideon Sample Number: UK231778-12133

Lucideon Report Number:	UK231778-12133/MFEP	Issue Number:	1
Date Logged:	16-May-2023	Order Number:	405269
Date Reported:	05-Jun-2023	Date(s) of Test(s):	20-May-2023 to 03-Jun-2023
	Ste	erility Testing	
	Memb	rane Filtration EP	

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

End of Test Report

DocuSigned by:

Natalie Boot

Signer Name: Natalie Boot Signing Reason: I have reviewed this document Signing Time: 05 June 2023 | 15:17 BST

-90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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