

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 23 August 2023

Product Name	CLEA	RKLENS TEGO 2000SC VH25
Product Code	100868202	
Batch Number	FMP23214	58105
Production Date	02/08/2023	
Expiration Date	EXP 02/08/2026	

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	its	Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
Specific Gravity (20°C)	DM004	0.993	1.003	1.000
pH (neat solution)	DM001	7.5	8.5	7.9

On behalf of Diversey site	Name:	Sabcho Svetoslavov Justyna Staron
Quality Manger	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

TCONTCHIPME VCISION , VT	COA Template	Version : 04	Date of issuing: March 11th 2019
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-39616A

Product Code Lot Number Quantity UOM
TEGO 2000SC DV4724 58105 151 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 58105. SAMPLE BOX 1 Case

Validation Reference Number: 4724

Processing Run Start Date: 16-Aug-2023 12:52 AM
Processing Run End Date: 16-Aug-2023 9:54 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 25.4

Reference Dose Range (kGy): 29.4 - 40.5 Calculated Max Dose (kGy): 33.6

All dosimeters measured within the required reference dose range to meet Customer dose specification.

PO Number: 406039

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

Gamma Process Run Approval authorized by STERIS

Date/Time: 16-Aug-2023 5:49 PM

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: 152546

N/A Last Revised in Rel 2.0.0.0 Rel Date: 13-Aug-2018 Page 1 of 1

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mr. Luka Davies

Report of Tests on: Tego 2000SC

Sample Description: Sample Code: Fmp23214 58105

Lucideon Sample Number: UK233175-24163

Lucideon Report Number: UK233175-24163/MFEP Issue Number: 1

Date Logged: 24-Aug-2023 Order Number: 406145

Date Reported: 11-Sep-2023 **Date(s) of Test(s):** 27-Aug-2023 **to** 10-Sep-2023

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

DocuSigned by:

Natalie Boot

Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 11 September 2023 | 12:06 BST

-90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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Certificate Pages: 1 Initials: 0 Natalie Boot

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Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Natalie.Boot@uk.lucideon.com

IP Address: 86.188.245.148

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11-Sep-23 | 12:04 Natalie.Boot@uk.lucideon.com

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Natalie Boot natalie.boot@uk.lucideon.com PlaceHolder	Natalie Boot	Sent: 11-Sep-23 12:05 Viewed: 11-Sep-23 12:06 Signed: 11-Sep-23 12:06
Lucideon Limited Security Level: Email, Account Authentication (Required), Authentication	Signature Adoption: Pre-selected Style Signature ID: 90369E90-4813-4123-B65D-5E8FBD375BF3 Using IP Address: 86.188.245.148	
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Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	11-Sep-23 12:05
Certified Delivered	Security Checked	11-Sep-23 12:06
Signing Complete	Security Checked	11-Sep-23 12:06
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Completed	Security Checked	11-Sep-23 12:06