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CERTIFICATE OF ANALYSIS

Date: 13 January 2025

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP24304	61336	
Production Date	30/10/2024		
Expiration Date	EXP 30/10/2027		

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	0.996
pH (neat solution)	DM001	7.5	8.5	8.2

On behalf of Diversey site Quality Manger	Name:	Justyna Staron	Kyle Ashton
	Position	Quality Control Inspector	

This document being issued electronically does not bear a signature

COA Template	Version : 04	Date of issuing : March 11th 2019
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STERIS : Manual Certificate Of Processing

Prepared For: Flexible Medical Packaging Ltd (8245)
Process Run ID: 2173-51834A

Inventory Details:

<u>Product Code</u>	<u>Pkg ID</u>	<u>Lot No.</u>	<u>Qty / UOM</u>
TEGO 2000SC DV4724	1	61336- STR001930, inc sample box	31 EA

PQ Specification:

PQ Reference: PQ4724
Dose measured at RML that is required to meet Customer Dose Specification:

<u>Dosimeter Location(s)</u>	<u>Minimum RML Dose (kGy)</u>	<u>Maximum RML Dose (kGy)</u>
RML, MAX	29.4	40.5

Process Outputs:

Irradiator: IR-150 Hydraulic Irradiator
Number of Dosimeters: 3

Dose from process run:

	<u>Irradiation Container</u>	<u>Dosimeter Location</u>	<u>Measured / Estimate</u>	<u>Delivered Dose (kGy)</u>	<u>Customer Dose Specification (kGy)</u>
MIN	Carrier #10	0CX588013241	Estimated Dose	25.0	25.0
MAX	Carrier #2	0CX588026719	Estimated Dose	45.0	45.0

Process Start: 13-Nov-2024 02:05am GMT
Process End: 13-Nov-2024 12:11pm GMT

Other Information:

Reference NC# NC-101434

Comments: First dosimeter of this run is not possible to read due to minor damage to the dosimeter. The last dosimeter from the run in front (2173-51671A) and surrounding dosimetry has been used for a dose estimate. Since the run in front is slightly different in density to the impacted run, it is not possible to establish a new calculated dose. It can only be confirmed that the affected run has received a dose within Customer dose specification.

Signature Manifest	
Quality Manager Approval / Date / Time (Print & Sign) <i>Mark Morse</i>	Electronically signed by: Mark Morse Reason: Approver Date: 12-Dec-2024 08:19 GMT
Quality Director Approval / Date / Time (Print & Sign) <i>[Signature]</i>	Electronically signed by: Claire Frogley Reason: Approver Date: 12-Dec-2024 08:25 GMT

Processing Location

Synergy Health Sterilization
UK Limited, a STERIS
Company
Brunel Close, Drayton Fields
Industrial Estate, Daventry,
Northants, NN11 8RB
Phone: +44(0) 1327 706 111

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used and/or Customer approval.

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 2000SC

Sample Description: Sample Code: Fmp24304 61336

Lucideon Sample Number: N25138 - 2

Lucideon Report Number: N25138 - 2/MFEP

Issue Number: 1

Date Logged: 14-Jan-2025

Order Number: 409742

Date Reported: 06-Feb-2025

Date(s) of Test(s): 17-Jan-2025 to 04-Feb-2025

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

Signed by:

Tracy Wheeler

Signer Name: Tracy Wheeler

Signing Reason: I have reviewed this document

Signing Time: 06 February 2025 | 14:13 GMT

D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler

Business Support Administrator

Page 1 of 1

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Certificate Of Completion

Envelope Id: AA416F0C-0A60-4AC7-99A2-3843609728AB	Status: Completed
Subject: sign	
Source Envelope:	
Document Pages: 2	Signatures: 2
Certificate Pages: 1	Initials: 0
AutoNav: Enabled	Envelope Originator:
Enveloped Stamping: Disabled	Tracy Wheeler
Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London	Queens Road
	Stoke-on-Trent, Staffordshire ST4 7LQ
	Tracy.Wheeler@uk.lucideon.com
	IP Address: 86.188.222.148

Record Tracking

Status: Original	Holder: Tracy Wheeler	Location: DocuSign
06-Feb-25 14:12	Tracy.Wheeler@uk.lucideon.com	

Signer Events

Tracy Wheeler
tracy.wheeler@uk.lucideon.com
Placeholder
Lucideon Limited
Security Level: Email, Account Authentication (Required), Authentication

Signature

Tracy Wheeler

Signature Adoption: Pre-selected Style
Signature ID:
D85AB024-6E18-4F31-821E-2EC1AFA6CA90
Using IP Address: 86.188.245.148

With Signing Authentication via Docusign password
With Signing Reasons (on each tab):
I have reviewed this document
I have reviewed this document

Timestamp

Sent: 06-Feb-25 | 14:13
Viewed: 06-Feb-25 | 14:13
Signed: 06-Feb-25 | 14:14

Electronic Record and Signature Disclosure:
Not Offered via Docusign

In Person Signer Events

Signature

Timestamp

Editor Delivery Events

Status

Timestamp

Agent Delivery Events

Status

Timestamp

Intermediary Delivery Events

Status

Timestamp

Certified Delivery Events

Status

Timestamp

Carbon Copy Events

Status

Timestamp

Witness Events

Signature

Timestamp

Notary Events

Signature

Timestamp

Envelope Summary Events

Status

Timestamps

Envelope Sent	Hashed/Encrypted	06-Feb-25 14:13
Certified Delivered	Security Checked	06-Feb-25 14:13
Signing Complete	Security Checked	06-Feb-25 14:14
Completed	Security Checked	06-Feb-25 14:14

Payment Events

Status

Timestamps