

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

## **CERTIFICATE OF ANALYSIS**

Date: 22 June 2023

Product Name	CLEA	CLEARKLENS CLEANSINALD SC VH9	
<b>Product Code</b>	101103552		
Batch Number	FMP23173	57586	
<b>Production Date</b>	22/06/2023		
<b>Expiration Date</b>	EXP 22/06/2025		

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
pH (neat solution)	DM001	12.0	13.0	12.7
Specific Gravity (20°C)	DM004	1.040	1.060	1.052
Cationic Content	DM020	14.25	15.75	15.49

On behalf of Diversey site Quality Manger	Name:	Sabcho Svetoslavov Ewelina Nowaczyk
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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

## STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-37922A

C/SINALD BOTTLES/CAPS/BAGS 57597 31 Case

**DV4894** 

Validation Reference Number: 4894

Processing Run Start Date: 10-Jun-2023 4:45 PM

Processing Run End Date: 10-Jun-2023 10:56 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 28.8

Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 35.0

PO Number: 405451

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

#### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 11-Jun-2023 7:27 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

Items irradiated under WO57597 will be used in finished batch Fmp23173 57586.

Olga Kirchner

Document ID: 146494

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 LA14XS

FAO: Mrs. Olga Kirchner

Report of Tests on:

Cleansinald SC

Sample Description:

Sample Code: Fmp23173 57586

Lucideon Sample Number: UK232387-16449

Lucideon Report Number: UK232387-16449/MFEP

**Issue Number:** 

**Date Logged:** 

28-Jun-2023

**Order Number:** 

405644

**Date Reported:** 

25-Jul-2023

Date(s) of Test(s):

06-Jul-2023

to 24-Jul-2023

**Sterility Testing Membrane 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:

Tracy Wheeles

Signer Name: Tracy Wheeler Signing Reason: I have reviewed this document Signing Time: 25 July 2023 | 11:47 BST D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler

**Business Support Administrator** 

Page 1 of 1

# **DocuSign**

#### **Certificate Of Completion**

Envelope Id: BA5084C8770A41CCB85186A2BFF8AB81

Subject: sign Source Envelope:

Document Pages: 2 Certificate Pages: 1

AutoNav: Enabled

Envelopeld Stamping: Disabled

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

Signatures: 2

Initials: 0

Tracy Wheeler Queens Road

> Stoke-on-Trent, Staffordshire ST4 7LQ Tracy.Wheeler@uk.lucideon.com IP Address: 86,188,245,148

#### **Record Tracking**

Status: Original

25-Jul-23 | 11:44

Holder: Tracy Wheeler

Tracy.Wheeler@uk.lucideon.com

Location: DocuSign

Sent: 25-Jul-23 | 11:46

Viewed: 25-Jul-23 | 11:47

Signed: 25-Jul-23 | 11:47

**Timestamp** 

Status: Completed

Envelope Originator:

### Signer Events

Tracy Wheeler

tracy.wheeler@uk.lucideon.com

PlaceHolder

Lucideon Limited

Security Level: Email, Account Authentication (Required), Authentication, Logged in

#### 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

# **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 Certified Delivered	Hashed/Encrypted Security Checked	25-Jul-23   11:46 25-Jul-23   11:47
Signing Complete	Security Checked	25-Jul-23   11:47
Completed	Security Checked	25-Jul-23   11:47
Payment Events	Status	Timestamps