

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 12 June 2023

<b>Product Name</b>	CLEA	CLEARKLENS CLEANSINALD SC VH9	
Product Code	7516429		
Batch Number	FMP23163	56825	
<b>Production Date</b>	12/06/2023		
<b>Expiration Date</b>	EXP 12/06/2025		

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	1.048
Cationic Content	DM020	14.25	15.75	15.73

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Ewelina Nowaczyk
	Position	Quality Control Inspector

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

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-37045A

Product Code <u>Lot Number</u> <u>Quantity</u> <u>UOM</u>

C/SINALD BOTTLES/CAPS/BAGS 56876 31 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 05-May-2023 3:16 PM

Processing Run End Date: 05-May-2023 9:47 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.5

Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 38.5

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: 05-May-2023 11:14 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

Items irradiated under WO56876 will be used in finished batch Fmp23163 56825.

Olga Kirchner.

Document ID: 142550

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: Fmp23163 56825

Lucideon Sample Number: UK232252-15392

Lucideon Report Number: UK232252-15392/MFEP

Issue Number:

1

**Date Logged:** 

16-Jun-2023

Order Number:

405542

Date Reported:

04-Jul-2023

Date(s) of Test(s):

20-Jun-2023 to 04-Jul-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: 04 July 2023 | 16:47 BST

90369E9048134123B65D6E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator** 

Page 1 of 1

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Natalie Boot Queens Road

Stoke-on-Trent, Staffordshire, ST4 7LQ

Natalie.Boot@uk.lucideon.com IP Address: 86.188.245.148

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04-Jul-23 | 16:44

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natalie.boot@uk.lucideon.com

PlaceHolder Lucideon Limited

Security Level: Email, Account Authentication

(Required), Authentication

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Signatures: 3

Initials: 0

Natalie Boot

Signature Adoption: Pre-selected Style

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Witness Events	Signature	Timestamp	
Notary Events	Signature	Timestamp	
Envelope Summary Events	Status	Timestamps	
Envelope Sent	Hashed/Encrypted	04-Jul-23   16:47	
Certified Delivered	Security Checked	04-Jul-23   16:47	
Signing Complete	Security Checked	04-Jul-23   16:48	
Completed	Security Checked	04-Jul-23   16:48	