

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 19 June 2023

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429		
Batch Number	FMP23170	58244	
Production Date	19/06/2023		
Expiration Date	EXP 19/06/2025		

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	1.050
Cationic Content	DM020	14.25	15.75	14.81

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Edyta Rodrígues
	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 Fmp23170 58244.

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: Fmp23170 58244

Lucideon Sample Number: UK232387-16448

Lucideon Report Number: UK232387-16448/MFEP

Issue Number:

1

Date Logged:

28-Jun-2023

Order Number:

405644

06-Jul-2023 to 24-Jul-2023

Date Reported:

25-Jul-2023

Date(s) of Test(s):

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:

Tracy Wheeler

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

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Status: Completed

Envelope Originator:

Tracy Wheeler Queens Road

Stoke-on-Trent, Staffordshire ST4 7LQ Tracy.Wheeler@uk.lucideon.com

IP Address: 86,188,245,148

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Signatures: 2

Initials: 0

Tracy.Wheeler@uk.lucideon.com

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Tracy Wheeler

tracy.wheeler@uk.lucideon.com

PlaceHolder Lucideon Limited

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Signature

Tracy Wheeler

Signature Adoption: Pre-selected Style

Signature ID:

Signature

Status

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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	25-Jul-23 11:46	
Certified Delivered	Security Checked	25-Jul-23 11:47	
Signing Complete	Security Checked	25-Jul-23 11:47	
Completed	Security Checked	25-Jul-23 11:47	