

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 28 June 2023

Product Name	CLEAF	CLEARKLENS CLEANSINALD SC VH9		
Product Code	101103552			
Batch Number	FMP23179	58320		
Production Date	28/06/2023			
Expiration Date	EXP 28/06/2025			

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:	Edyta Rodrígues Justyna Staron
	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 2173-37922A

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

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 Fmp23179 58320.

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 LA1 4XS

FAO: Mr. Luka Davies

Report of Tests on:

Cleansinald SC

Sample Description:

Sample Code FMP23179 58320

Lucideon Sample Number: UK232501-18841

Lucideon Report Number: UK232501-18841/MFEP

Issue Number:

Date Logged:

30-Jun-2023

Order Number:

405662

Date Reported:

27-Jul-2023

Date(s) of Test(s):

12-Jul-2023

to 26-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:

Notable Boot

Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 27 July 2023 | 11:32 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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Document Pages: 2

Certificate Pages: 1 AutoNav: Enabled

Envelopeld Stamping: Disabled

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

Envelope Originator: Signatures: 2 Initials: 0 Natalie Boot

Queens Road

Status: Completed

Stoke-on-Trent, Staffordshire ST4 7LQ

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

Record Tracking

Status: Original

27-Jul-23 | 11:30

Holder: Natalie Boot

Natalie.Boot@uk.lucideon.com

Location: DocuSign

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Signer Events

Natalie Boot

natalie.boot@uk.lucideon.com

PlaceHolder

Lucideon Limited

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Signature

Notalie Boot

Signature Adoption: Pre-selected Style

Signature ID:

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Status	Timestamp	
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Hashed/Encrypted	27-Jul-23 11:32	
Security Checked	27-Jul-23 11:32	
Security Checked	27-Jul-23 11:32	
Security Checked	27-Jul-23 11:32	
Status	Timestamps	
	Status Status Status Status Status Signature Signature Status Hashed/Encrypted Security Checked Security Checked Security Checked	