

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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# **CERTIFICATE OF ANALYSIS**

Date: 07 September 2023

Product Name	CLEARKLENS CLEANSINALD SS VH9S	
<b>Product Code</b>	100848254	
Batch Number	FMP23250 58363	
<b>Production Date</b>	07/09/2023	
<b>Expiration Date</b>	EXP 07/03/2025	

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	<b>Test Method</b>	Limi	ts	Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	9.0	11.4	10.9
Specific Gravity (20°C)	DM004	0.990	1.010	0.997

On behalf of Diversey site	Name:	Sabcho Svetoslavov Justyna Staron
Quality Manger	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

TCONTCHINIALC TOTAL DATE OF ISSUING, MAICH FILL 2017	COA Template	Version : 04	Date of issuing: March 11th 2019
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# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-39044A

C/SINALD SS 900ml Bottle DV4673 58365 13 Case

Validation Reference Number: 4673

Processing Run Start Date: 20-Jul-2023 10:20 PM

Processing Run End Date: 21-Jul-2023 4:52 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 30.8

Reference Dose Range (kGy): 27.3 - 36.6 Calculated Max Dose (kGy): 37.5

All dosimeters measured within the required reference dose range to meet Customer dose specification.

PO Number: 405817

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

## Signature Manifest

Reviewed and E-Signed By: Tamas Szatmari (Quality Engineer)

Date/Time E-Signed: 24-Jul-2023 10:45 AM

**Document Content Revision: 1** 

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 WO58365 will be used in finished batch Fmp23250 58363.

Olga Kirchner

Document ID: 150535

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: Mrs. Olga Kirchner

Report of Tests on: Cleansinald SS

Sample Description: Sample Code: Fmp23250 58363

Lucideon Sample Number: UK233416-25609

Lucideon Report Number: UK233416-25609/MFEP Issue Number: 1

Date Logged: 14-Sep-2023 Order Number: 406277

**Date Reported:** 05-Oct-2023 **Date(s) of Test(s):** 19-Sep-2023 **to** 03-Oct-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: 05 October 2023 | 14:25 BST 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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Status: Completed

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Subject: Sign Source Envelope:

Document Pages: 1 Signatures: 1 Envelope Originator:

Certificate Pages: 1 Initials: 0 Natalie Boot
AutoNav: Enabled Queens Road

Envelopeld Stamping: Disabled Stoke-on-Trent, Staffordshire ST4 7LQ

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

Natalie.Boot@uk.lucideon.com

IP Address: 86.188.245.148

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05-Oct-23 | 14:24 Natalie.Boot@uk.lucideon.com

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natalie.boot@uk.lucideon.com	Natalie Boot	Viewed: 05-Oct-23   14:25	
PlaceHolder		Signed: 05-Oct-23   14:25	
Lucideon Limited	Signature Adoption: Pre-selected Style		
Security Level: Email, Account Authentication (Required), Authentication, Logged in	Signature ID:		
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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	05-Oct-23   14:25
Certified Delivered	Security Checked	05-Oct-23   14:25
Signing Complete	Security Checked	05-Oct-23   14:25
Completed	Security Checked	05-Oct-23   14:25
Payment Events	Status	Timestamps