

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 29 November 2023

Product Name	CLEARKLENS CLEANSINALD SS VH9S	CLEARKLENS CLEANSINALD SS VH9S		
<b>Product Code</b>	100848254			
Batch Number	FMP23331 59136			
<b>Production Date</b>	27/11/2023			
<b>Expiration Date</b>	EXP 27/05/2025			

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	9.0	11.4	10.5
Specific Gravity (20°C)	DM004	0.990	1.010	0.996

On behalf of Diversey site Quality Manger	Name:	Edyta Rodrígues
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

TCONTCHIPME VCISION , VT	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 2173-42122A

Product CodeLot NumberQuantityUOMC/SINALD SS 900ml Bottle DV467359145 - STR00F10613 Case

Validation Reference Number: 4673

Processing Run Start Date: 11-Nov-2023 8:02 AM

Processing Run End Date: 11-Nov-2023 2:25 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 28.3

Reference Dose Range (kGy): 27.3 - 36.6 Calculated Max Dose (kGy): 34.1

PO Number: 406776

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

### Gamma Process Run Approval authorized by STERIS

Date/Time: 11-Nov-2023 4:08 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 WO59145 will be used in finished batch Fmp23331 59136.

Olga Kirchner

Document ID: 160184

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

Mrs. Olga Kirchner FAO:

Test Results:

Report of Tests on: Cleansinald SS

**Sample Description:** Sample Code: Fmp23331 59136

Lucideon Sample Number: UK234412-33452

Lucideon Report Number: UK234412-33452/MFEP Issue Number:

**Order Number: Date Logged:** 406976 01-Dec-2023

Date(s) of Test(s): 21-Dec-2023 05-Dec-2023 to 19-Dec-2023 Date Reported:

> **Sterility Testing** Membrane Filtration EP

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: 21 December 2023 | 15:51 GMT 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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**Envelope Originator:** 

Natalie Boot

Queens Road

Stoke-on-Trent, Staffordshire ST4 7LQ

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21-Dec-23 | 15:48

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Natalie Boot

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Envelope Sent Certified Delivered Signing Complete Completed	Hashed/Encrypted Security Checked Security Checked Security Checked	21-Dec-23   15:50 21-Dec-23   15:50 21-Dec-23   15:51 21-Dec-23   15:51
Payment Events	Status	Timestamps