

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 06 July 2023

<b>Product Name</b>	CLEA	CLEARKLENS CLEANSINALD SS VH9S		
Product Code	100848254			
Batch Number	FMP23187	57650		
<b>Production Date</b>	06/07/2023			
<b>Expiration Date</b>	EXP 06/01/2025			

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	Limi	ts	Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	9.0	11.4	10.8
Specific Gravity (20°C)	DM004	0.990	1.010	0.998

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

This document being issued electronically does not bear a signature

COA Template	Version: 04	Date of issuing: March 11th 2019

# **STERIS: Gamma Certificate Of Processing**

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-38112A

C/SINALD SS 900ml Bottle DV4673 57666 13 Case

Validation Reference Number: 4673

Processing Run Start Date: 16-Jun-2023 9:35 AM

Processing Run End Date: 16-Jun-2023 8:46 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 30.0

Reference Dose Range (kGy): 27.3 - 36.6 Calculated Max Dose (kGy): 36.7

PO Number: 405509

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

## Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 16-Jun-2023 10:10 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 WO57666 will be used in finished batch Fmp23187 57650.

Olga Kirchner

Document ID: 146997

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: Fmp23187 57650

Lucideon Sample Number: UK232615-19933

Lucideon Report Number: UK232615-19933/MFEP Issue Number: 1

Date Logged: 11-Jul-2023 Order Number: 405754

**Date Reported:** 03-Aug-2023 **Date(s) of Test(s):** 19-Jul-2023 **to** 02-Aug-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: 03 August 2023 | 14:37 BST 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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Document Pages: 1 Signatures: 1 Envelope Originator:

Certificate Pages: 1 Initials: 0 Natalie Boot
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Natalie.Boot@uk.lucideon.com IP Address: 86.188.245.148

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Witness Events	Signature	Timestamp	
Notary Events	Signature	Timestamp	
Envelope Summary Events	Status	Timestamps	
Envelope Sent	Hashed/Encrypted	03-Aug-23   14:37	
Certified Delivered	Security Checked	03-Aug-23   14:37	
Signing Complete	Security Checked	03-Aug-23   14:37	
Completed	Security Checked	03-Aug-23   14:37	
Payment Events	Status	Timestamps	