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## **CERTIFICATE OF ANALYSIS**

Date: 07 February 2023

Product Name	CLEA	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429			
Batch Number	FMP23038	56048		
<b>Production Date</b>	07/02/2023			
<b>Expiration Date</b>	EXP 07/02/2025			

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	12.8
Specific Gravity (20°C)	DM004	1.040	1.060	1.048
Cationic Content	DM020	14.25	15.75	14.81

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

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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

2173-34519A

**Product Code** 

**Lot Number** 

Quantity

C/SINALD BOTTLES/CAPS/BAGS

56064

**UOM** 

DV4894

Validation Reference Number:

30 Case

4894

Processing Run Start Date: 27-Jan-2023 12:51 PM

Processing Run End Date: 27-Jan-2023 7:08 PM

Specified Dose Range (kGy):

25.0 - 40.0

Calculated Min Dose (kGy):

28.4

Reference Dose Range (kGy):

27.4 - 36.5

Calculated Max Dose (kGy):

34.8

PO Number: 404384

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

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 28-Jan-2023 6:29 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

Item irradiated under WO56064 will be used in finished batch Fmp23038 56048.

Olga Kirchner

Document ID: 134059

Rel Date: 13-Aug-2018 Page 1 of 1 Last Revised in Rel 2.0.0.0

# 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: Fmp23038 56048

Lucideon Sample Number: UK23513-3550

Lucideon Report Number: UK23513-3550/MFEP

Issue Number:

Date Logged:

13-Feb-2023

Order Number:

404565

**Date Reported:** 

07-Mar-2023

Date(s) of Test(s):

17-Feb-2023 to 07-Mar-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** 

NOBOOK ON MON 23

Mrs Natalie Boot

Senior Business Support Administrator