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## CERTIFICATE OF ANALYSIS

Date: 06 February 2023

|                 |                               |       |  |
|-----------------|-------------------------------|-------|--|
| Product Name    | CLEARKLENS CLEANSINALD SC VH9 |       |  |
| Product Code    | 7516429                       |       |  |
| Batch Number    | FMP23037                      | 57072 |  |
| Production Date | 06/02/2023                    |       |  |
| Expiration Date | EXP 06/02/2025                |       |  |

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 | 1.050                        |
| Cationic Content        | DM020       | 14.25                        | 15.75 | 15.25                        |

|  |          |  |
|--|----------|--|
| On behalf of Diversey site<br>Quality Manger | Name:    | Justyna Staron      Angelika Partynska |
|  | 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 2173-34522A

| <u>Product Code</u>                  | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|--------------------------------------|-------------------|-----------------|------------|
| C/SINALD BOTTLES/CAPS/BAGS<br>DV4894 | 55878             | 15              | Case       |
| Validation Reference Number: 4894    |                   |                 |            |

Processing Run Start Date: 27-Jan-2023 9:42 AM

Processing Run End Date: 27-Jan-2023 3:24 PM

|                             |             |                            |      |
|-----------------------------|-------------|----------------------------|------|
| Specified Dose Range (kGy): | 25.0 - 40.0 | Calculated Min Dose (kGy): | 27.7 |
| Reference Dose Range (kGy): | 27.4 - 36.5 | Calculated Max Dose (kGy): | 34.4 |

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: 27-Jan-2023 6:20 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 sterile under WO55878 will be used in finished batch Fmp23037 57072

Olga Kirchner

Document ID: 134009

N/A

Last Revised in Rel 2.0.0.0

Rel Date: 13-Aug-2018

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# PHARMACEUTICAL ANALYSIS REPORT

# LUCIDEON

insight creating advantage

## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Mrs.Olga Kirchner

**Report of Tests on:** Cleansinald SC

**Sample Description:** Sample Code: Fmp23037 57072

**Lucideon Sample Number:** UK23481-3294

**Lucideon Report Number:** UK23481-3294/MFEP

**Issue Number:** 1

**Date Logged:** 09-Feb-2023

**Order Number:** 404538

**Date Reported:** 06-Mar-2023

**Date(s) of Test(s):** 15-Feb-2023 to 05-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**

*Natalie Boot 06 Nov 23*

Mrs Natalie Boot

**Senior Business Support Administrator**

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