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## CERTIFICATE OF ANALYSIS

Date: 16 November 2022

|                 |                                |       |  |
|-----------------|--------------------------------|-------|--|
| Product Name    | CLEARKLENS CLEANSINALD SS VH9S |       |  |
| Product Code    | 100848254                      |       |  |
| Batch Number    | FMP22320                       | 55343 |  |
| Production Date | 16/11/2022                     |       |  |
| Expiration Date | EXP 16/05/2024                 |       |  |

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  | 10.8                         |
| Specific Gravity (20°C) | DM004       | 0.990                        | 1.010 | 0.998                        |

|  |          |                                       |
|--|----------|---------------------------------------|
| On behalf of Diversey site<br>Quality Manger | Name:    | Edyta Rodrigues    Angelika Partynska |
|  | Position | Quality Control Inspector             |

*This document being issued electronically does not bear a signature*

|              |              |                                      |
|--------------|--------------|--------------------------------------|
| COA Template | Version : 02 | Date of issuing : November 24th 2017 |
|--------------|--------------|--------------------------------------|

# 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 SS

**Sample Description:** Sample Code: Fmp22320 55343

**Lucideon Sample Number:** UK224557-29718

**Lucideon Report Number:** UK224557-29718/MFEP **Issue Number:** 1

**Date Logged:** 21-Nov-2022 **Order Number:** 403989

**Date Reported:** 12-Dec-2022 **Date(s) of Test(s):** 24-Nov-2022 to 08-Dec-2022

### 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**

NCR001 12-DEC-22

Mrs Natalie Boot

**Senior Business Support Administrator**

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

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## STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)  
Gamma Process Run ID 2173-31027A

| <u>Product Code</u>               | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|-----------------------------------|-------------------|-----------------|------------|
| C/SINALD SS 900ml Bottle DV4673   | 55375             | 13              | Case       |
| Validation Reference Number: 4673 |                   |                 |            |

Processing Run Start Date: 10-Sep-2022 7:14 AM

Processing Run End Date: 10-Sep-2022 1:31 PM

|                             |             |                            |      |
|-----------------------------|-------------|----------------------------|------|
| Specified Dose Range (kGy): | 25.0 - 40.0 | Calculated Min Dose (kGy): | 29.0 |
| Reference Dose Range (kGy): | 27.3 - 36.6 | Calculated Max Dose (kGy): | 35.5 |

PO Number: 403374

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

**Gamma Process Run Approval authorized by STERIS**

Date/Time E-Signed: 10-Sep-2022 4:59 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 WO55375 will be used in finished batch Fmp22320 55343.

Olga Kirchner

Document ID: 122005

N/A

Last Revised In Rel 2.0.0.0

Rel Date: 13-Aug-2018

Page 1 of 1