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## CERTIFICATE OF ANALYSIS

Date: 07.12.2020

|                 |                                |
|-----------------|--------------------------------|
| Product Name    | CLEARLENSE CLEANSINALD SS VH9S |
| Product Code    | 100848254                      |
| Batch Number    | FMP 20342 51200                |
| Production Date | 07.12.2020                     |
| Expiration Date | EXP 07/06/2022                 |

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  | 10.7                         |
| Specific Gravity (20°C) | DM004       | 0.990                        | 1.010 | 0.997                        |

|   |          |                           |
|---|----------|---------------------------|
| On behalf of Diversey site<br>Quality Manager | Name :   | Itawan, A. Bony           |
|   | Position | Quality Control Inspector |

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

|              |              |  |
|--------------|--------------|--|
| COA Template | Version : 02 | Date of issuing : November 24 <sup>th</sup> 2017 |
|--------------|--------------|--|



STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-15109A

| <u>Product Code</u>               | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|-----------------------------------|-------------------|-----------------|------------|
| C/SINALD SS 900ml Bottle DV4673   | WO50733           | 13              | Case       |
| Validation Reference Number: 4673 |                   |                 |            |

Processing Run Start Date: 14-Nov-20 05:32 PM

Processing Run End Date: 14-Nov-20 11:13 PM

|                             |             |                            |      |
|-----------------------------|-------------|----------------------------|------|
| Specified Dose Range (kGy): | 25.0 - 40.0 | Calculated Min Dose (kGy): | 29.3 |
| Reference Dose Range (kGy): | 27.3 - 36.6 | Calculated Max Dose (kGy): | 36.5 |

PO Number: 36803

Gamma Process Run Approval authorized by STERIS

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 WO50733 will be used in finished batch Fmp20342 51200.

Olga Kirchner



# 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: FMP20342 51200

**Lucideon Sample Number:** UK205049-35214

**Lucideon Report Number:** UK205049-35214/MFEP **Issue Number:** 1

**Date Logged:** 10-Dec-2020 **Order Number:** PO 36990

**Date Reported:** 15-Feb-2021 **Date(s) of Test(s):** 28-Jan-2021 to 11-Feb-2021

### 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**

*No Book 15-Feb-21*

Mrs Natalie Boot

**Business Support Administrator**

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