

Diversey Europe Operations BV Maarasenbroeksedijk 2 3642 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date:

14 November 2022

| Product Name    | CLEARKLENS CLEANSINALD SS VH9S |       |  |
|-----------------|--------------------------------|-------|--|
| Product Code    | 100848254                      |       |  |
| Batch Number    | FMP22314                       | 55059 |  |
| Production Date | 10/11/2022                     |       |  |
| Expiration Date | EXP 10/05/2024                 |       |  |

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         | 0.997                        |

| On behalf of Diversey site Quality Manger | Name:    | Edyta Rodrígues Urszula Haraburda |
|---|----------|-----------------------------------|
|   | Position | Quality Control Inspector         |

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

# **STERIS: Gamma Certificate Of Processing**

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-29723A

C/SINALD SS 900ml Bottle DV4673 55085 13 Case

Validation Reference Number: 4673

Processing Run Start Date: 14-Jul-2022 11:07 PM

Processing Run End Date: 15-Jul-2022 5:27 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 30.5

Reference Dose Range (kGy): 27.3 - 36.6 Calculated Max Dose (kGy): 37.6

PO Number: 403001

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

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 15-Jul-2022 6:55 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

Items irradiated under WO55085 will be used in finished batch Fmp22314 55059.

Olga Kirchner

Document ID: 117096

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: Fmp22314 55059

Lucideon Sample Number: UK224527-29560

Lucideon Report Number: UK224527-29560/MFEP

Issue Number:

1

Date Logged:

17-Nov-2022

Order Number:

403970

Date Reported:

08-Dec-2022

Date(s) of Test(s):

22-Nov-2022 to 06-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** 



Mrs Natalie Boot

Senior Business Support Administrator