

Diversay Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utracht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 15 January 2020

| Product Name | CLEARKLENS CLEANSINALD SC VH9 | |
|-----------------|-------------------------------|-------|
| Product Code | 7516429 | |
| Batch Number | FMP20015 | 49215 |
| Production Date | 15/01/2020 | |
| Expiration Date | EXP 15/01/2022 | |

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 | Limi Lower | its - Upper | Results |
|-------------------------|-------------|----------------|----------------|------------------------------|
| Appearance | Visual | Clear Slightly | Yellow Liquid | Clear Slightly Yellow Liquid |
| pH (neat solution) | DM001 | 12.0 | 13.0 | 12.9 |
| Specific Gravity (20°C) | DM004 | 1.040 | 1.060 | 1.052 |
| Catonic content | DM020 | 14.25 | 15.75 | 14.51 |

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

This document being issued electronically does not bear a signature

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-7121A

| Product Code | Lot Number | Quantity | <u>UOM</u> |
|--------------------------------------|-------------|----------------------------|------------|
| C/SINALD BOTTLES/CAPS/BAGS DV4894 | WO48801 | 16 | Case |
| Validation Reference Number: 4894 | | | |
| Processing Run Start Date: 27-Dec-19 | 05:10 PM | | |
| Processing Run End Date: 27-Dec-19 | 11:35 PM | | |
| Specified Dose Range (kGy): | 25.0 - 40.0 | Calculated Min Dose (kGy): | 29.1 |
| Reference Dose Range (kGy): | 27.4- 36.5 | Calculated Max Dose (kGy): | 35.1 |

PO Number: PO34486

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

Signature Manifest

Reviewed and E-Signed By: Bhavya Ramisetty (Quality Engineer)

Date/Time E-Signed: 2019-12-30 10:36 AM

Document Content Revision: 1

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 WO48801 will mbe used in finished batch Fmp20015 49215.

Olga Kirchner

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 SC

Sample Description: Sample Code: Fmp20015 49215

12-Mar-2020

Lucideon Sample Number: UK20478-3786

Lucideon Report Number: UK20478-3786/MFEP

Date Logged: 31-Jan-2020

Date Reported:

Order Number:

Issue Number:

Date(s) of Test(s): <u>Sterility Testing</u> Membrane Filtration EP PO 34687

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16-Feb-2020 to 03-Mar-2020

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

Joboot 12 Mar-20

Mrs Natalie Boot Senior Business Support Assistant

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