Diversey Europe Operations BV
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# CERTIFICATE OF ANALYSIS

Date: 21. 11. 18

| | |
|---|---|
| **Product Name** | **CLEARKLENS CLEANSINALD SS VH9S** |
| **Product Code** | 10084 8254 |
| **Batch Number** | FHP 18325 46226 |
| **Production Date** | 21 \| 11 \| 2018 |
| **Expiration Date** | Exp. 21 \| 05 \| 2020 |

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 Lower | Limits Upper | Results |
|---|---|---|---|---|
| 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 | 0.996 |

| | | |
|---|---|---|
| On behalf of Diversey site Quality Manager | Name : | Deepa Kanchna, M. Mahabarde |
| | Position | Quality Control Inspector |

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

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

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

**Date Received:** 29 Nov 2018
**Date Tested:** 05 Dec 2018
**Date Test Completed:** 19 Dec 2018
**Purchase Order:** 32214

# CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0046063/2
**Test Required:** Sterility by Membrane Filtration Steritest
**Date Received:** 29/11/2018
**Test Article:** Clearklens Cleansinald SS
**Sample Code:** FMP18325 46226
**Batch Ref:** 9690
**Qty Received:** 20 x 900mL Bottles

| Test | Method Item | Result |
|---|---|---|
| Sterility Test by Membrane Filtration (Steritest) Method | MM107/00 | Pass |
| Growth in Tryptone Soya Broth at 20-25°C after 14 days | MM107/01 | No growth in one broth |
| Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days | MM107/02 | No growth in one broth |
| Volume Tested | MM107/05 | 20 x 50 mL |
| Tested in Accordance with Ph Eur, USP & JP | MQ005/07 | EP 9.0 2.6.1, USP 41 <71> & JP XVII 4.06 |
| Product Standard Data Sheet | FG047/psd | FM06-01 |

## Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name and position is shown below.

CBiol MRSB

Date: 20 Dec 2018 16:27:33

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

STERIS

http://www.steris-ast.com

# Certificate of Irradiation

**Date Issued: 11-Nov-2018** **UK33S12191842-2-1**

**This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:**

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

**Flexible Medical Packaging Ltd**
**Unit 8, White Cross Ind Estate**
**Hightown**
**Lancaster**
**Lancashire LA1 4XS**
**UNITED KINGDOM**

**All in accordance with current Technical Agreement**

## Order Information

| | |
|---|---|
| Account Number: | 100432 |
| Synergy Health Sales Part Reference: | 1105380 |
| Customer Reference Number: | P032021 |
| Product Description: | C/SINALD SS 900ml Bottle DV4673 25-40kGy |
| Validation Reference: | 4673 |
| Quantity Received: | 6 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 40.0 |
| Customer Unit Lot/Batch Number: | W046227, 1 PLT |

## Irradiation Data

| | |
|---|---|
| Date and Time of Irradiation: | 11-Nov-2018 23:23 |
| Reference Dose Range kGy: | 32.9 - 33.0 |
| Calculated Minimum Dose kGy: | 30.2 |
| Calculated Maximum Dose kGy: | 36.1 |

Items irradiated under WO46227, will be used in finished product batch FMP18325 46226.

C Pascoe

**Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company**