



Diversey Europe BV

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The Netherlands

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## CERTIFICATE OF ANALYSIS

Date: 02.09.2015

|                 |                               |
|-----------------|-------------------------------|
| Product Name    | CLEARLENSE CLEANSINALD SC VH9 |
| Product Code    | 7516429                       |
| Batch Number    | FMP15213 38642                |
| Production Date | 01/08/2015                    |
| Expiration Date | 01/08/2017                    |

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 (100% 20°C)          | JDM001      | 12.0   | 13.0                   | 12.8                         |
| Specific Gravity (20°C) | JDM004      | 1.040  | 1.060                  | 1.050                        |
|                         |             |        |                        |                              |

|   |          |                           |
|---|----------|---------------------------|
| On behalf of Diversey site<br>Quality Manager | Name :   | H. Unbeek                 |
|   | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

|             |              |  |
|-------------|--------------|--|
| COA 7516429 | Version : 03 | Date of issuing : November 28 <sup>th</sup> 2011 |
|-------------|--------------|--|



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date issued: 21-Jul-2015

UK2S11423779-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 Sterilisation of Health Care Products  
 EN ISO 9001:2008 Quality Management System  
 EN ISO 13485:2012 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: | 1002719                                     |
| Customer Reference Number:           | PO24691                                     |
| Product Description:                 | C/SINALD BLK BOTT/CAPS/BAGS 25-40kGy        |
| Validation Reference:                | 4.1666                                      |
| Quantity Received:                   | 11  |
| Customer Minimum Specification kGy:  | 25.0  |
| Customer Maximum Specification kGy:  | 40.0  |
| Customer Unit Lot/Batch Number:      | B/N WO38545 THURS 9TH JULY 2015 1 PLT LOT 2 |

## Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 21-Jul-2015 01:54 |
| Reference Dose Range kGy:     | 33.8 - 35.1       |
| Calculated Minimum Dose kGy:  | 27.3              |
| Calculated Maximum Dose kGy:  | 36.1              |

Items Irradiated under WO38545 will be used in finished product batch code FMP15213 38642

*L. Gwyn* 04.08.2015

Irradiation Release Authorised By Synergy Health plc

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



# Wickham Laboratories

Contract Analytical Services

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

**Date Received:** 06 Aug 2015  
**Date Tested:** 14 Aug 2015  
**Date Test Completed:** 28 Aug 2015  
**Purchase Order:** PO24873

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0024063/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 06/08/2015  
**Test Article:** Cleansinald sc  
**Sample Code:**  
**Batch Ref:** FMP15213 38642  
**Qty Received:** 20 x 25mL 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 25 mL             |
| Product Standard Data Sheet                                    | FG047/psd   | FM06                   |

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 01 Sep 2015 16:56:20

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology