



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 14.04.2014

| | |
|-----------------|-------------------------------|
| Product Name | CLEARLENSE CLEANSINALD SC VH9 |
| Product Code | 7516429 |
| Batch Number | FMP 14104 36012 |
| Production Date | 04 / 2014 |
| Expiration Date | 04 / 2016 |

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 | 13.0 |
| Specific Gravity (20°C) | JDM004 | 1.040 | 1.060 | 1.050 |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | Olga Kirchner, C. Piscoe |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

| | | |
|-------------|--------------|--|
| COA 7516429 | Version : 03 | Date of issuing : November 28 th 2011 |
|-------------|--------------|--|



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 04-Apr-2014

UK32S11129501-1-1

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: | P021912 |
| Product Description: | C/SINALD BLK BOTT/CAPS/BAGS 25-40kGy |
| Validation Reference: | 4.0616 |
| Quantity Received: | 11 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 40.0 |
| Customer Unit Lot/Batch Number: | W036013 THURS 13.03.14 2 PLTS LOT 4 |
| Other Process Details: | Validation ref 4.1666 carried out on this consignment. |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 30-Mar-2014 02:25 |
| Reference Dose Range kGy: | 36.0 - 37.2 |
| Calculated Minimum Dose kGy: | 29.8 |
| Calculated Maximum Dose kGy: | 38.1 |

Items irradiated under W036013 will be used in finished product batch code FMP14104 36012

E. Gangey 17.04.14

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

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

Date Received: 17 Apr 2014
Date Tested: 27 Apr 2014
Date Test Completed: 11 May 2014
Purchase Order: PO22123

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0016197/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 17/04/2014
Test Article: ClearKlens Cleansinald SC Block
Sample Code: 458800
Batch Ref: FMP14104 36012
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: 12 May 2014 17:25:25

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0016197

Certificate of Analysis - OSMM

Print Number: P0019778

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ISO
17025

GLP GMP FDA

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