



Diversey Europe BV  
 Maarssebroeksedijk 2  
 3542 DN Utrecht  
 The Netherlands  
 Tel. +31 (0)30 247 6427

### CERTIFICATE OF ANALYSIS

Date: 05/01/2017

|                 |                   |
|-----------------|-------------------|
| Product Name    | CLEARLENs IPA VH1 |
| Product Code    | 7513400           |
| Batch Number    | FMP 16335 41828   |
| Production Date | 30/11/2016        |
| Expiration Date | EXP 30/11/2018    |

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 Colourless Liquid |       | Clear Colourless Liquid |
| Specific Gravity (20°C) | JDM004      | 0.872                   | 0.883 | 0.880                   |
|                         |             |                         |       |                         |

|  |          |                           |
|--|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name :   | <i>Pauyisla, W...</i>     |
|  | Position | Quality Control Inspector |

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

|             |              |  |
|-------------|--------------|--|
| COA 7513400 | Version : 03 | Date of issuing : November 28 <sup>th</sup> 2017 |
|-------------|--------------|--|



<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 22-Dec-2016

UK33S11767960-1-1

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

EN ISO 11137-1:2015 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

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### Order Information

|                                      |   |
|--------------------------------------|---|
| Account Number:                      | 100432                                    |
| Synergy Health Sales Part Reference: | 1104747                                   |
| Customer Reference Number:           | 27896                                     |
| Product Description:                 | IPA BOTTLE DV4648 25-45kGy                |
| Validation Reference:                | 4648                                      |
| Quantity Received:                   | 706                                       |
| Customer Minimum Specification kGy:  | 25.0                                      |
| Customer Maximum Specification kGy:  | 45.0                                      |
| Customer Unit Lot/Batch Number:      | FMP16335 41828, PROVIDE 4 SAMPLES, 13PLTS |

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### Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 22-Dec-2016 01:38 |
| Reference Dose Range kGy:     | 34.5 - 36.8       |
| Calculated Minimum Dose kGy:  | 27.3              |
| Calculated Maximum Dose kGy:  | 41.6              |

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Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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



<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date issued: 07-Jan-2017

UK33S11777994-1-1

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

EN ISO 11137-1:2015 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

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### Order Information

|                                      |                            |
|--------------------------------------|----------------------------|
| Account Number:                      | 100432                     |
| Synergy Health Sales Part Reference: | 1104747                    |
| Customer Reference Number:           | P028007                    |
| Product Description:                 | IPA BOTTLE DV4648 25-45kGy |
| Validation Reference:                | 4648                       |
| Quantity Received:                   | 708                        |
| Customer Minimum Specification kGy:  | 25.0                       |
| Customer Maximum Specification kGy:  | 45.0                       |
| Customer Unit Lot/Batch Number:      | FMP16335 41828, 13 PLTS    |

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### Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 06-Jan-2017 22:52 |
| Reference Dose Range kGy:     | 34.8 - 35.9       |
| Calculated Minimum Dose kGy:  | 27.5              |
| Calculated Maximum Dose kGy:  | 40.6              |

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Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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



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

**Date Received:** 05 Jan 2017  
**Date Tested:** 10 Jan 2017  
**Date Test Completed:** 10 Jan 2017  
**Purchase Order:** 28027

**CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 0033110/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 05/01/2017  
**Test Article:** Clearklens IPA  
**Sample Code:** FMP16335 41828  
**Batch Ref:** 8184  
**Qty Received:** 1 x 900mL

| Test                                       | Method Item | Result                                   |
|--|-------------|--|
| Bacterial Endotoxin by Kinetic QCL Test    | MM110/00    | <0.2 EU/mL                               |
| Spiked Recovery                            | MM110/01    | 92 %                                     |
| Dilution Tested                            | MM110/04    | 1/40                                     |
| Endotoxin Spike Level                      | MM110/02    | 0.5 EU/mL                                |
| Tested in Accordance with Ph Eur, USP & JP | MQ005/07    | EP 9.0 2.6.14, USP 39 <85> & JPXVII 4.01 |
| Product Standard Data Sheet                | FG047/psd   | FM02                                     |

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

Date: 11 Jan 2017 13:06:10

Mrs P. Pham-Lengoc  
Laboratory Manager - Pharmaceutical Microbiology



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

**Date Received:** 05 Jan 2017  
**Date Tested:** 11 Jan 2017  
**Date Test Completed:** 25 Jan 2017  
**Purchase Order:** 28027

**CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 0033110/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 05/01/2017  
**Test Article:** Clearlens IPA  
**Sample Code:** FMP16335 41828  
**Batch Ref:** 8184  
**Qty Received:** 20 x 900mL (+1 Spare)

| 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    | See external comments  |
| Product Standard Data Sheet                                    | FG047/psd   | FM03                   |

**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.

Date: 26 Jan 2017 11:30:57

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology