



Diversey Europe Operations BV

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The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 10/10/2017

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP17265 43372
Production Date	22/09/2017
Expiration Date	EXP 22/09/2019

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>Barbara Karakula</i>
	Position	Quality Control Inspector

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

COA 7513400	Version : 04	Date of issuing : April 27 <sup>th</sup> 2012
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 07-Oct-2017

UK33S11978978-1-1

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

## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1104747
Customer Reference Number:	PO29717
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	986
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17265 43372, 18 PLTS

## Irradiation Data

Date and Time of Irradiation:	07-Oct-2017 18:35
Reference Dose Range kGy:	36.3 - 36.9
Calculated Minimum Dose kGy:	28.7
Calculated Maximum Dose kGy:	41.8

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

# Certificate of Irradiation

Date Issued: 01-Oct-2017

UK33S11973518-1-2

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:	P029689
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	436
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17265 43372, INC 4 SAMPLES, 8 pils

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## Irradiation Data

Date and Time of Irradiation:	01-Oct-2017 07:24
Reference Dose Range kGy:	35.5 - 36.8
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	41.6

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Irradiation Release Authorised By Synergy Health plc

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

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# 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:** 09 Oct 2017  
**Date Tested:** 10 Oct 2017  
**Date Test Completed:** 10 Oct 2017  
**Purchase Order:** 29750

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0038411/1  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 09/10/2017  
**Test Article:** Clearklens IPA  
**Sample Code:** FMP17265 43372  
**Batch Ref:** 8825  
**Qty Received:** 1 x 900mL Bottle

Test	Method Item	Result	Specification
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL	
Spiked Recovery	MM110/01	85 %	50-200
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 40 <85> & JPXVII 4.01	
Product Standard Data Sheet	FG047/psd	FM02	

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

 BSc. CBiol. MRSB

Date: 11 Oct 2017 13:55:01

Mrs P. Pham-Lengoc  
Laboratory Manager - Pharmaceutical Microbiology



# Wickham Laboratories

Contract Analytical Services

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

**Date Received:** 09 Oct 2017  
**Date Tested:** 11 Oct 2017  
**Date Test Completed:** 25 Oct 2017  
**Purchase Order:** 29750

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0038411/2  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 09/10/2017  
**Test Article:** Clearklens IPA  
**Sample Code:** FMP17265 43372  
**Batch Ref:** 8825  
**Qty Received:** 20 x 900mL Bottles (+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.

C Moore MRSB

Date: 26 Oct 2017 12:15:06

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology