



Diversey Europe BV

Maarssebroekdijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 11.04.2016

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP 16079 40066
Production Date	19/03/2016
Expiration Date	EXP 19/03/2018

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	0.879

On behalf of Diversey site Quality Manager	Name :	Panteyida, C. K. K. K.
	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> 2011
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 04-Apr-2016

UK32S11596103-1-1

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

EN ISO 11137-1:2015 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:	1002734
Customer Reference Number:	P026281
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1971
Quantity Received:	1097
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1093 X BATCH NO FMP16079 40066 + 4 SAMPLES FRI 1ST APR 2016 21 PLTS LOT 1

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## Irradiation Data

Date and Time of Irradiation:	03-Apr-2016 14:48
Reference Dose Range kGy:	35.1 - 38.4
Calculated Minimum Dose kGy:	25.3
Calculated Maximum Dose kGy:	39.9

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Irradiation Release Authorised By Synergy Health plc

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Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

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: 01-Apr-2016

UK32S11591189-1-1

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

EN ISO 11137-1:2015 Sterilisation of Health Care Products  
EN ISO 9001:2008 Quality Management System  
EN ISO 13485:2012 Quality System - Medical Devices

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UNITED KINGDOM

All in accordance with current Technical Agreement

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## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1002734
Customer Reference Number:	P026252
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1971
Quantity Received:	324
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BATCH NO: FMP16079 40066 THURS 24TH MAR 2016 6 PLTS LOT 4

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## Irradiation Data

Date and Time of Irradiation:	01-Apr-2016 04:41
Reference Dose Range kGy:	35.8 - 37.3
Calculated Minimum Dose kGy:	25.8
Calculated Maximum Dose kGy:	38.7

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Irradiation Release Authorised By Synergy Health plc

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Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

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:** 11 Apr 2016  
**Date Tested:** 15 Apr 2016  
**Date Test Completed:** 29 Apr 2016  
**Purchase Order:** 26337

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0028312/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 11/04/2016  
**Test Article:** Clearklens IPA  
**Sample Code:** FMP16079 40066  
**Batch Ref:** 7525  
**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	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: 29 Apr 2016 16:18:08

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



# Wickham Laboratories

Contract Analytical Services

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Ms D Henderson  
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Unit 8  
Hightown  
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Lancaster  
LA1 4XS

**Date Received:** 11 Apr 2016  
**Date Tested:** 13 Apr 2016  
**Date Test Completed:** 13 Apr 2016  
**Purchase Order:** 26337

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0028312/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 11/04/2016  
**Test Article:** Clearklens IPA  
**Sample Code:** FMP16079 40066  
**Batch Ref:** 7525  
**Qty Received:** 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	64 %
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 8.0 2.6.14, USP 38 <85> & JP XVI 4.01
Product Standard Data Sheet	FG047/psd	FM02

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

Date: 14 Apr 2016 09:16:02

Mrs P. Pham-Lengoc  
Laboratory Manager - Pharmaceutical Microbiology