



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427  
www.Diversey.com

## CERTIFICATE OF ANALYSIS

Date: 23.05.2018

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP18118 / 45155
Production Date	28/04/2018
Expiration Date	EXP 28/04/2020

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)	DM004	0.872	0.883	0.876

On behalf of Diversey site Quality Manager	Name :	J. Stouwenberg
	Position	Quality Control Inspector

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

COA Template	Version : 02	Date of issuing : November 24 <sup>th</sup> 2017
--------------	--------------	--



<http://www.steris-ast.com>

## Certificate of Irradiation

Date Issued: 21-May-2018

UK33S12105840-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 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:	P031034
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	560
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18118 45155, 11 PLTS

### Irradiation Data

Date and Time of Irradiation:	21-May-2018 14:03
Reference Dose Range kGy:	35.7 - 36.8
Calculated Minimum Dose kGy:	28.2
Calculated Maximum Dose kGy:	41.6

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

## Certificate of Irradiation

Date Issued: 14-May-2018

UK33S12104781-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 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:	P031016
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	869
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18118, 45155, INC 5 SAMPLES, 16 PLTS

---

### Irradiation Data

Date and Time of Irradiation:	14-May-2018 18:18
Reference Dose Range kGy:	35.1 - 37.0
Calculated Minimum Dose kGy:	27.7
Calculated Maximum Dose kGy:	41.9

---

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

---

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



# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
Fax: +44(0)1329 226688

mail@wickhamlabs.co.uk  
www.wickhamlabs.co.uk

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

**Date Received:** 22 May 2018  
**Date Tested:** 23 May 2018  
**Date Test Completed:** 23 May 2018  
**Purchase Order:** 31093

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0042791/1  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 22/05/2018  
**Test Article:** Clearklens IPA  
**Sample Code:** FMP18118 45155  
**Batch Ref:** 9357  
**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	103 %
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 9.3 2.6.14, USP 41 <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: 24 May 2018 09:47:16

Mrs P. Pham-Lengoc  
Laboratory Manager - Pharmaceutical Microbiology



# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
Fax: +44(0)1329 226688

mail@wickhamlabs.co.uk  
www.wickhamlabs.co.uk

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

**Date Received:** 22 May 2018  
**Date Tested:** 01 Jun 2018  
**Date Test Completed:** 15 Jun 2018  
**Purchase Order:** 31093

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0042791/2  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 22/05/2018  
**Test Article:** Clearklens IPA  
**Sample Code:** FMP18118 45155  
**Batch Ref:** 9357  
**Qty Received:** 20 x 900mL Bottle (+ 1 Spares)

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	EP 9.0 2.6.1, USP 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM03

### Comments

Additional samples received the 29.05.18, Clearklens IPA, Sample Code FMP18118 45155, Batch Ref 9357, Quantity 2 x 900mL Bottles have been allocated lab ref LR0042791/2A.

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.

CBiol MRSB

Date: 15 Jun 2018 16:27:56

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology