

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 22 08.2018

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	FMP18213 - 45358
<b>Production Date</b>	01/08/2018
<b>Expiration Date</b>	EXP 01108/2020

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	Lin	nits	Results
		Lower -	Upper	<u></u>
Appearance	Visual	Clear Co Liq		clear Colourless
Specific Gravity (20°C)	DM004	0.872	0.883	0.876

	Name:	M. Maraburda Partyust
On behalf of Diversey site  Quality Manager	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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



http://www.steris-ast.com

# **Certificate of Irradiation**

Date Issued: 20-Aug-2018

UK33S12152691-1-2

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:	31567		
Product Description:	IPA BOTTLE DV4648 25-45kGy		
Validation Reference:	4648		
Quantity Received:	615		
Customer Minimum Specification kGy:	25.0		
Customer Maximum Specification kGy:	45.0		
Customer Unit Lot/Batch Number:	FMP18213, 45358, 12 PLTS		
- II	rradiation Data		
Date and Time of Irradiation:	20-Aug-2018 10:59		
Reference Dose Range kGy:	35.3 - 36.2		
Calculated Minimum Dose kGy:	27.9		
Calculated Maximum Dose kGy:	41.0		

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

**A2** 



http://www.steris-ast.com

# **Certificate of Irradiation**

Date Issued: 13-Aug-2018

UK33S12149936-2-1

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

Fiexible 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:	P031508		
Product Description:	IPA BOTTLE DV4648 25-45kGy		
Validation Reference:	4648		
Quantity Received:	815		
Customer Minimum Specification kGy:	25.0		
Customer Maximum Specification kGy:	45.0		
Customer Unit Lot/Batch Number:	FMP18213 45358, INC 5 SMPLS, 15 PLTS		
lı .	rradiation Data		
Date and Time of Irradiation:	13-Aug-2018 02:43		
Reference Dose Range kGy:	35.0 - 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



Wickham Laboratories Ltd Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

Telephone: Fax: +44(0)1329 226600 +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:

23 Aug 2018

**Date Tested:** 

28 Aug 2018

Date Test Completed:

11 Sep 2018

**Purchase Order:** 

31616

### **CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 

0044372/2

**Test Required:** 

Sterility by Membrane Filtration Steritest

Date Received:

23/08/2018

Test Article:

Clearklens IPA

Sample Code:

FMP18213 45358

Batch Ref:

9545

**Qty Received:** 

20 x 900mL Bottles (+ 2 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	FM03-01

#### **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.

1'ASSE BSc. CBiol. MRSB

Date: 12 Sep 2018 13:58:24

Mrs P. Pham-Lengoc

Laboratory Manager - Pharmaceutical Microbiology

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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:

23 Aug 2018

Date Tested:

24 Aug 2018

Date Test Completed:

24 Aug 2018

**Purchase Order:** 

31616

## **CERTIFICATE OF ANALYSIS**

Laboratory Reference Number:

0044372/1

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL

Date Received: Test Article: 23/08/2018

Clearklens IPA FMP18213 45358

Sample Code: Batch Ref:

9545

**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	95 %
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.

Maria

CBiol, MRSB

Date: 29 Aug 2018 09:07:57

Mrs C Moore

Laboratory Manager - Pharmaceutical Microbiology

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