Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 23/04/2018

Product Name	**CLEARKLENS IPA VH1**
Product Code	75134OO
Batch Number	FMP 18094 45006
Production Date	04/04/2018
Expiration Date	EXP 04/04/2020

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 Lower - Upper	Results
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 :	Wawbrda Partyuska
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	*Version : 02*	*Date of issuing : November 24th 2017*

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 16-Apr-2018 **UK33S12091148-2-1**

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:	P030825
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:	FMP18094 45006, INC 5 SAMPLES, 15 PLTS

Irradiation Data

Date and Time of Irradiation:	16-Apr-2018 06:45
Reference Dose Range kGy:	36.3 - 37.0
Calculated Minimum Dose kGy:	28.7
Calculated Maximum Dose kGy:	41.9

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

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 24-Apr-2018 **UK33S12094852-1-1**

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

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UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1104747
Customer Reference Number:	po30856
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	614
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18094, 45006, 12 PLTS

Irradiation Data

Date and Time of Irradiation:	24-Apr-2018 06:43
Reference Dose Range kGy:	35.8 - 37.7
Calculated Minimum Dose kGy:	28.3
Calculated Maximum Dose kGy:	42.7

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

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: 24 Apr 2018
Date Tested: 26 Apr 2018
Date Test Completed: 26 Apr 2018
Purchase Order: 30921

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0042283/1
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 24/04/2018
Test Article: Clearklens IPA
Sample Code: FMP18094 45006
Batch Ref: 9282
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	83 %
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 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: 27 Apr 2018 09:10:51

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA

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: 24 Apr 2018
Date Tested: 30 Apr 2018
Date Test Completed: 14 May 2018
Purchase Order: 30921

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0042283/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 24/04/2018
Test Article: Clearklens IPA
Sample Code: FMP18094 45006
Batch Ref: 9282
Qty Received: 20 x 900mL Bottles (2 x 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 40 <71> & JP XVII 4.06
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.

CBiol MRSB Date: 15 May 2018 14:46:28

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA