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The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 15/12/2017

Product Name	CLEARKLENS IPA VH1
Product Code	7514372
Batch Number	FMP 17326 43721
Production Date	22/11/2017
Expiration Date	EXP 22/11/2019

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)	DM004	0.872	0.883	0.876

On behalf of Diversey site Quality Manager	Name :	Pantjists, Manabunda
	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
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# Wickham Laboratories

Contract Analytical Services

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

**Date Received:** 19 Dec 2017  
**Date Tested:** 29 Jan 2018  
**Date Test Completed:** 12 Feb 2018  
**Purchase Order:** 30178

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0039931/2  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 19/12/2017  
**Test Article:** Clearlens IPA  
**Sample Code:** FMP17326 43721  
**Batch Ref:** 8988  
**Qty Received:** 27 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

Replacement Samples received 05.01.18, 6 x bottles have been allocated to LR: 0039931/2A (2 are spares).

Four bottles leaking, one leaking bottle used for test after confirmation with client, four leaking bottles to be returned to client.

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: 13 Feb 2018 13:04:39

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



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Ms D Henderson  
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LA1 4XS

**Date Received:** 19 Dec 2017  
**Date Tested:** 21 Dec 2017  
**Date Test Completed:** 21 Dec 2017  
**Purchase Order:** 30178

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0039931/1  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 19/12/2017  
**Test Article:** Clearlens IPA  
**Sample Code:** FMP17326 43721  
**Batch Ref:** 8988  
**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	58 %
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. CSiol. MRSB

Date: 21 Dec 2017 16:04:03

Mrs P. Pham-Lengoc  
Laboratory Manager - Pharmaceutical Microbiology



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

## Certificate of Irradiation

Date Issued: 03-Dec-2017

UK33S12021752-2-1

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  
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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:	P030042
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	544
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17326 43721, INC 4 SAMPLES, 10 plts

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### Irradiation Data

Date and Time of Irradiation:	03-Dec-2017 11:59
Reference Dose Range kGy:	36.0 - 37.5
Calculated Minimum Dose kGy:	28.5
Calculated Maximum Dose kGy:	42.4

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

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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: 11-Dec-2017

UK33S12026268-2-1

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

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### Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1104747
Customer Reference Number:	P030094
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	142
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17326 43721, 3 plts

### Irradiation Data

Date and Time of Irradiation:	10-Dec-2017 20:52
Reference Dose Range kGy:	36.8 - 37.7
Calculated Minimum Dose kGy:	29.1
Calculated Maximum Dose kGy:	42.7

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