Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 01.07.2019

Product Name	**CLEARKLENS IPA VH1**
Product Code	7513400
Batch Number	FHP 19 119 46927
Production Date	29.04.2019
Expiration Date	EXP 29/04/2021

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	0.873

On behalf of Diversey site Quality Manager	Name :	J. Stavon, Quality cntrl
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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

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: 02 Jul 2019
Date Tested: 04 Jul 2019
Date Test Completed: 04 Jul 2019
Purchase Order: 33403

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0049455/1
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 02/07/2019
Test Article: Clearklens IPA
Sample Code: FMP19119 46927
Batch Ref: 10228
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	79 %
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 42 <85> & JPXVII 4.01
Product Standard Data Sheet	FG047/psd	FM02-01

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

BSc. CBiol MRSB

Date: 08 Jul 2019 11:31:30

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

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

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www.wickhamlabs.co.uk

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Flexible Medical Packaging Limited
Unit 8
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White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 02 Jul 2019
Date Tested: 26 Jul 2019
Date Test Completed: 09 Aug 2019
Purchase Order: 33403

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0049455/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 02/07/2019
Test Article: Clearklens IPA
Sample Code: FMP19119 46927
Batch Ref: 10228
Qty Received: 20 x 900mL Bottles + 1 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	FM03-02

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.

BSc. CBiol MRSB

Date: 12 Aug 2019 15:35:14

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

GMP GLP FDA Audited Laboratory

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3631A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19119 46927	378	Case
Validation Reference Number:	4648		
IPA BOTTLE DV4648	FMP19119 46927, inc 1 envelope labelled "SAMPLE"	54	Case
Validation Reference Number:	4648		

PO Number: PO33208

Processing Run Start Date: 13-Jun-19 11:28 PM

Processing Run End Date: 14-Jun-19 09:30 AM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**27.1**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**39.6**

Signature Manifest

Reviewed and E-Signed By: **Mark Morse (QA Officer)**

Date/Time E-Signed: 2019-06-18 11:25 AM

Document Content Revision: 1

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3500A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19119 46927	756	Case
Validation Reference Number: 4648			
IPA BOTTLE DV4648	FMP19119 46927 SAMPLES	5	Case
Validation Reference Number: 4648			

PO Number: PO33153

Processing Run Start Date: 22-Jun-19 05:41 AM

Processing Run End Date: 23-Jun-19 12:46 AM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**26.1**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**40.5**

Signature Manifest

Reviewed and E-Signed By: **Mark Morse (QA Officer)**

Date/Time E-Signed: 2019-06-24 11:16 AM

Document Content Revision: 1

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111