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CERTIFICATE OF ANALYSIS

Date: 30/04/2019

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP 19094 46928
Production Date	04/04/2019
Expiration Date	EXP 04/04/2021

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		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.872	0.883	0.877

On behalf of Diversey site Quality Manager	Name :	Pauyels, J. Staven
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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

Contract Analytical Services

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

Date Received: 30 Apr 2019
Date Tested: 30 May 2019
Date Test Completed: 13 Jun 2019
Purchase Order: 33025

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0048473/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 30/04/2019
Test Article: Claerklens IPA
Sample Code: FMP19094 46928
Batch Ref: 10159
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	FM03-02

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: 18 Jun 2019 15:59:16

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology



Wickham Laboratories

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LA1 4XS

Date Received: 30 Apr 2019
Date Tested: 03 May 2019
Date Test Completed: 03 May 2019
Purchase Order: 33025

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0048473/1
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 30/04/2019
Test Article: Clearklens IPA
Sample Code: FMP19094 46928
Batch Ref: 10159
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	80 %
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.



Date: 03 May 2019 15:54:21

Victoria Watson
Laboratory Manager – Microbiology

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-2791A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
DIVER DE BLK2 BOTTLE DV4648	FMP19094 46928	702	Case
Validation Reference Number: 4648			

Processing Run Start Date: 02-May-19 06:53 AM

Processing Run End Date: 02-May-19 06:02 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.7
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	40.7

Other Information

FMP19094 46928, 13 PLTS

Gamma Process Run Approval authorized by STERIS

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: 2173-2705A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
IPA BOTTLE DV4648	FMP19094 46928	378	Case
Validation Reference Number: 4648			
IPA BOTTLE DV4648	FMP19094 46928 INC 5 SAMPLES	5	Case
Validation Reference Number: 4648			

PO Number: PO32901

Processing Run Start Date: 24-Apr-19 08:47 AM

Processing Run End Date: 24-Apr-19 05:55 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.9
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	40.5

Gamma Process Run Approval authorized by STERIS

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: 2173-2867A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
DIVER DE BLK2 BOTTLE DV4648	FMP19094 46928	348	Case
Validation Reference Number: 4648			

Processing Run Start Date: 02-May-19 05:16 AM

Processing Run End Date: 02-May-19 02:25 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.7
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	40.3

Other Information

FMP19094 46928, 7 PLTS

Gamma Process Run Approval authorized by STERIS

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