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CERTIFICATE OF ANALYSIS

Date: 28.11.2018

Product Name	CLEARLENs IPA VH1
Product Code	100885705
Batch Number	FHD 18813 46397
Production Date	09/11/2018
Expiration Date	Exp. 09/11/2020

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		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 :	ago Larcene, Pantyus
	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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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-779A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
IPA BOTTLE DV4648	FMP18313 46397	216	Case
Validation Reference Number: 4648			
IPA BOTTLE DV4648	FMP18313 46397 SAMPLES	5	Case
Validation Reference Number: 4648			

Processing Run Start Date: 20-Nov-18 07:09 AM

Processing Run End Date: 20-Nov-18 05:07 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.8
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	40.7

Other Information

FMP18313 46397, INC 5 SAMPLES, 4 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 Dosimetry Record
FLEXIBLE MEDICAL PACKAGING LTD (8245)

Run ID: 2173-779A

Irradiator / Method: IR-150 Hydraulic Irradiator - ON-STD

<u>Carrier-Seg</u>	<u>Coordinate</u>	<u>Batch (Cal Date)</u>	<u>Spectro S/N</u>	<u>Micro S/N</u>	<u>Absorbance</u>	<u>Thickness</u>	<u>Final Dose (kGy)</u>	<u>Comment</u>
1-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.883	2.9120	36.0	
19-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.837	2.7907	35.2	
37-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.897	2.9756	35.6	

Minimum Reference Dose for Record (kGy): 35.2

Maximum Reference Dose for Record (kGy): 36.0

Last Dosimeter Measurement Date: 2018-11-21 01:07 AM

Signature Manifest

Prepared By: **Andrian Perju (Operator)**

Date/Time E-Signed: 2018-11-21 01:07 AM

Document Content Revision: 1

Processing Location

Synergy Health Sterilisation UK
Limited, a STERIS Company
Brunel Close
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Comment Legend: OUT = Calculated Dose Outside Allowable Limits Provided By Process Specification

Document ID: 8854

Last Revised in Rel 2.0.0.0

Rel Date: 08/13/2018

Page 1 of 1

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-831A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
IPA BOTTLE DV4648	FMP18313 46397	492	Case

Validation Reference Number: 4648

PO Number: PO32171

Processing Run Start Date: 27-Nov-18 12:54 PM

Processing Run End Date: 27-Nov-18 10:34 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.6
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	39.9

Other Information

FMP18313 46397, 9 PLTS

Signature Manifest

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

Date/Time E-Signed: 2018-11-28 08:26 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
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NN11 8RB
Phone: + 44(0) 1327 706 111

STERIS: Gamma Dosimetry Record
FLEXIBLE MEDICAL PACKAGING LTD (8245)

Run ID: 2173-831A

Irradiator / Method: IR-150 Hydraulic Irradiator - ON-STD

<u>Carrier-Seq</u>	<u>Coordinate</u>	<u>Batch (Cal Date)</u>	<u>Spectro S/N</u>	<u>Micro S/N</u>	<u>Absorbance</u>	<u>Thickness</u>	<u>Final Dose (kGy)</u>	<u>Comment</u>
1-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.810	2.7099	34.9	
17-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.876	2.9158	35.3	
34-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.818	2.7344	35.0	
51-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.836	2.7834	35.3	
68-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.878	2.9293	35.2	
82-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.823	2.7440	35.2	

Minimum Reference Dose for Record (kGy): 34.9

Maximum Reference Dose for Record (kGy): 35.3

Last Dosimeter Measurement Date: 2018-11-28 02:28 AM

Signature Manifest

Prepared By: **Dave Ledger (Supervisor)**

Date/Time E-Signed: 2018-11-28 02:34 AM

Document Content Revision: 1

Processing Location

Synergy Health Sterilisation UK
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Comment Legend: OUT = Calculated Dose Outside Allowable Limits Provided By Process Specification

Document ID: 9034

Last Revised in Rel 2.0.0.0

Rel Date: 08/13/2018

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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: 29 Nov 2018
Date Tested: 03 Dec 2018
Date Test Completed: 03 Dec 2018
Purchase Order: 32214

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0046063/4
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 29/11/2018
Test Article: Clearklens IPA
Sample Code: FMP18313 46397
Batch Ref: 9814
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	60 %
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	FM02-01

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

Date: 04 Dec 2018 16:19:23

Victoria Watson
Laboratory Manager – Microbiology



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 29 Nov 2018
Date Tested: 07 Dec 2018
Date Test Completed: 21 Dec 2018
Purchase Order: 32214

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0046063/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 29/11/2018
Test Article: Clearklens IPA
Sample Code: FMP18313 46397
Batch Ref: 9814
Qty Received: 20 x 900mL Bottles + 3 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.

 CBIOL MRSB

Date: 28 Dec 2018 08:09:51

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology