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CERTIFICATE OF ANALYSIS

Date: 13/12/2018

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP 18331 46550
Production Date	27/11/2018
Expiration Date	EXP 27/11/2020

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	0.880

On behalf of Diversey site Quality Manager	Name :	<i>Pauline H. H. H. H. H.</i>
	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: 2173-943A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
IPA BOTTLE DV4648	FMP18331 46550	756	Case
Validation Reference Number: 4648			
IPA BOTTLE DV4648	FMP18331 46550 INC 1 SAMPLE	1	Case
Validation Reference Number: 4648			

Processing Run Start Date: 12-Dec-18 12:06 AM

Processing Run End Date: 12-Dec-18 11:24 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.3
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	40.1

Other Information

FMP18331 46550, INC 1 SAMPLE, 14 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: 2173-943A

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	0.887	2.9481	35.4	
19-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.933	3.1331	34.7	
38-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.906	3.0341	34.9	
57-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.954	3.1998	34.8	
76-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.866	2.9130	34.5	
95-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.927	3.1063	34.8	
114-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.885	2.9412	35.4	
127-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.921	3.0717	35.2	

Minimum Reference Dose for Record (kGy): 34.5

Maximum Reference Dose for Record (kGy): 35.4

Last Dosimeter Measurement Date: 2018-12-12 02:09 PM

Signature Manifest

Prepared By: **Steve Brown (Operator)**

Date/Time E-Signed: 2018-12-12 02:10 PM

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: 9835

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: 2173-1001A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
IPA BOTTLE DV4648	FMP18331 46550	562	Case

Validation Reference Number: 4648

Processing Run Start Date: 19-Dec-18 06:18 AM

Processing Run End Date: 19-Dec-18 07:04 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	26.8
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	39.8

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
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Phone: + 44(0) 1327 706 111

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

Run ID: 2173-1001A

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	0.868	2.8949	35.2	
19-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.868	2.8967	35.1	
38-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.861	2.8823	34.9	
57-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.838	2.8447	33.9	
76-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.839	2.8433	34.0	
94-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.836	2.8157	34.4	

Minimum Reference Dose for Record (kGy): 33.9

Maximum Reference Dose for Record (kGy): 35.2

Last Dosimeter Measurement Date: 2018-12-19 11:32 PM

Signature Manifest

Prepared By: **Steve Brown (Operator)**

Date/Time E-Signed: 2018-12-19 11:33 PM

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

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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: 2173-892A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
IPA BOTTLE DV4648	FMP18331 46550	108	Case
Validation Reference Number: 4648			
IPA BOTTLE DV4648	FMP18331 46550 PROVIDE 5 SAMPLES	5	Case
Validation Reference Number: 4648			

PO Number: PO32209

Processing Run Start Date: 03-Dec-18 05:15 PM

Processing Run End Date: 04-Dec-18 12:57 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	26.6
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	38.9

Other Information

FMP18331 46550, INC 5 SMPLS, 2 PLTS

Signature Manifest

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

Date/Time E-Signed: 2018-12-13 10:54 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

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Phone: + 44(0) 1327 706 111

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

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

Run ID: 2173-892A

<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	0.846	2.8815	33.6	
10-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.940	3.1841	34.0	
19-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.913	3.0748	34.4	

Minimum Reference Dose for Record (kGy): 33.6

Maximum Reference Dose for Record (kGy): 34.4

Last Dosimeter Measurement Date: 2018-12-04 05:59 AM

Signature Manifest

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

Date/Time E-Signed: 2018-12-04 06:00 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: 9512

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Rel Date: 08/13/2018

Page 1 of 1



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

Date Received: 14 Dec 2018
Date Tested: 27 Dec 2018
Date Test Completed: 10 Jan 2019
Purchase Order: 32300

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0046349/3
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 14/12/2018
Test Article: Clearklens IPA
Sample Code: FMP18331 46550
Batch Ref: 9823
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	FM03-01

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.

 BSc CBiol MRSB

Date: 14 Jan 2019 14:46:34

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology



Wickham Laboratories

Contract Analytical Services

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Date Received: 14 Dec 2018
Date Tested: 18 Dec 2018
Date Test Completed: 18 Dec 2018
Purchase Order: 32300

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0046349/4
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 14/12/2018
Test Article: Clearlens IPA
Sample Code: FMP18331 46550
Batch Ref: 9823
Qty Received: 1 x 900mL Bottles

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	84 %
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: 20 Dec 2018 09:22:29

Victoria Watson
Laboratory Manager – Microbiology