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The Netherlands

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www.Diversey.com

## CERTIFICATE OF ANALYSIS

Date: 28.01.2019

Product Name	CLEARKLENS IPA VH1
Product Code	4513400
Batch Number	FHP19002, 46553
Production Date	02.01.2019
Expiration Date	EXP 02/01/2021

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	0.847

On behalf of Diversey site Quality Manager	Name :	Karaburda Pantyuslo
	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  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
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Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 29 Jan 2019  
**Date Tested:** 11 Feb 2019  
**Date Test Completed:** 25 Feb 2019  
**Purchase Order:** 32496

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0046950/2  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 29/01/2019  
**Test Article:** Clearkens IPA Sprays  
**Sample Code:** FMP19002 46553  
**Batch Ref:** 9822  
**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.

C Biol MMSB

Date: 26 Feb 2019 16:20:21

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



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LA1 4XS

**Date Received:** 29 Jan 2019  
**Date Tested:** 31 Jan 2019  
**Date Test Completed:** 31 Jan 2019  
**Purchase Order:** 32496

## **CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 0046950/3  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 29/01/2019  
**Test Article:** Clearklens IPA Sprays  
**Sample Code:** FMP19002 46553  
**Batch Ref:** 9822  
**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	54 %
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.

*Watson*

Date: 01 Feb 2019 15:48:19

Victoria Watson  
Laboratory Manager – Microbiology

# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1161A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
IPA BOTTLE DV4648	FMP19002	972	Case
Validation Reference Number: 4648			
IPA BOTTLE DV4648	FMP19002 SAMPLES	5	Case
Validation Reference Number: 4648			

PO Number: PO32378

Processing Run Start Date: 13-Jan-19 04:01 AM

Processing Run End Date: 13-Jan-19 03:22 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	26.9
Reference Dose Range (kGy):	31.6- 39.8	Calculated Max Dose (kGy):	40.7

## Other Information

FMP19002 46553, INC 5 SMPLS, 18 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: 2173-1265A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
IPA BOTTLE DV4648	FMP19002 46553	448	Case

Validation Reference Number: 4648

PO Number: PO32425

Processing Run Start Date: 20-Jan-19 04:20 AM

Processing Run End Date: 20-Jan-19 01:21 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):	41.2

### Signature Manifest

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

Date/Time E-Signed: 2019-01-21 09:41 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

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