Diversey Europe Operations BV
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The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 13|08|2018

Product Name	**CLEARKLENS DE VH29**
Product Code	100862174
Batch Number	FMP 18209 45280
Production Date	28|07|2018
Expiration Date	EXP 28|07|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 Lower - Upper	Results
Appearance	Visual	Clear Colourless Liquid	Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.880 0.888	0.884

On behalf of Diversey site Quality Manager	Name :	Partyka, Mariola
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 13-Aug-2018 **UK33S12149936-1-1**

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

Flexible Medical Packaging Ltd
Unit 8, White Cross Ind Estate
Hightown
Lancaster
Lancashire LA1 4XS
UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Account Number:	**100432**
Synergy Health Sales Part Reference:	**1106483**
Customer Reference Number:	**P031508**
Product Description:	**DIVER DE BLK2 BOTTLE DV4648 25-45kGy**
Validation Reference:	**4648**
Quantity Received:	**161**
Customer Minimum Specification kGy:	**25.0**
Customer Maximum Specification kGy:	**45.0**
Customer Unit Lot/Batch Number:	**FMP18209 45280, 3 PLTS**

Irradiation Data

Date and Time of Irradiation:	**13-Aug-2018 02:49**
Reference Dose Range kGy:	**36.3 - 37.0**
Calculated Minimum Dose kGy:	**28.7**
Calculated Maximum Dose kGy:	**41.9**

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 05-Aug-2018 **UK33S12147272-2-1**

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

Flexible Medical Packaging Ltd
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UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Account Number:	**100432**
Synergy Health Sales Part Reference:	**1106483**
Customer Reference Number:	**P031482**
Product Description:	**DIVER DE BLK2 BOTTLE DV4648 25-45kGy**
Validation Reference:	**4648**
Quantity Received:	**545**
Customer Minimum Specification kGy:	**25.0**
Customer Maximum Specification kGy:	**45.0**
Customer Unit Lot/Batch Number:	**FMP18209 45280, INC 5 SMPLS, 10 PLTS**

Irradiation Data

Date and Time of Irradiation:	**05-Aug-2018 12:22**
Reference Dose Range kGy:	**35.9 - 36.4**
Calculated Minimum Dose kGy:	**28.4**
Calculated Maximum Dose kGy:	**41.2**

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company **A2**

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White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 14 Aug 2018
Date Tested: 15 Aug 2018
Date Test Completed: 15 Aug 2018
Purchase Order: PO31543

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0044225/1
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 14/08/2018
Test Article: Clearklens DE
Sample Code: FMP18209 45280
Batch Ref: 9544
Qty Received: 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.25 EU/mL
Spiked Recovery	MM110/01	77 %
Dilution Tested	MM110/04	1/50
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	FM01-01

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

BSc, CBiol, MRSB

Date: 23 Aug 2018 12:46:29

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA

Company Registered in England No. 752951

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Date Received: 14 Aug 2018
Date Tested: 17 Aug 2018
Date Test Completed: 31 Aug 2018
Purchase Order: PO31543

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0044225/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 14/08/2018
Test Article: Clearklens DE
Sample Code: FMP18209 45280
Batch Ref: 9544
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	FM03-01

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: 31 Aug 2018 16:32:32

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA Company Registered in England No. 752951