



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 17.11.2017

Product Name	CLEARKLENS DE VH29
Product Code	100862174
Batch Number	FMP 17299 43536
Production Date	26/10/2017
Expiration Date	EXP 26/10/2019

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)	JDM004	0.880	0.888	0.888

On behalf of Diversey site Quality Manager	Name :	U. Haraburda Potyishko
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

COA 100862174	Version : 02	Date of issuing : July 1 <sup>st</sup> 2017
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# Wickham Laboratories

Contract Analytical Services

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

**Date Received:** 15 Nov 2017  
**Date Tested:** 16 Nov 2017  
**Date Test Completed:** 16 Nov 2017  
**Purchase Order:** 29977

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0039181/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 15/11/2017  
**Test Article:** Clearklens DE  
**Sample Code:** FMP17299 43536  
**Batch Ref:** 8923  
**Qty Received:** 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	2.5665 EU/mL
Spiked Recovery	MM110/01	88 %
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 9.0 2.6.14, USP 40<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: 17 Nov 2017 15:18:40

Mrs P. Pham-Lengoc  
Laboratory Manager - Pharmaceutical Microbiology



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**Date Received:** 15 Nov 2017  
**Date Tested:** 14 Dec 2017  
**Date Test Completed:** 28 Dec 2017  
**Purchase Order:** 29977

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0039181/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 15/11/2017  
**Test Article:** Clearklens DE  
**Sample Code:** FMP17299 43536  
**Batch Ref:** 8923  
**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

### 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 2017 15:56:58

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date issued: 05-Nov-2017

UK33S12000231-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products

EN ISO 9001:2008 Quality Management System

EN ISO 13485:2012 Quality System - Medical Devices

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

All in accordance with current Technical Agreement

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## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1106483
Customer Reference Number:	P029885
Product Description:	DIVER DE BLK2 BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	707
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP 17299 43536, Inc 4 Samples, 13 plts

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## Irradiation Data

Date and Time of Irradiation:	04-Nov-2017 18:32
Reference Dose Range kGy:	37.0 - 37.5
Calculated Minimum Dose kGy:	29.2
Calculated Maximum Dose kGy:	42.4

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Irradiation Release Authorised By Synergy Health plc

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Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069