



Diversey Europe BV

Maarseebroekedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 10.05.2016

Product Name	CLEARKLENS DE VH29
Product Code	7515783
Batch Number	FMP 16105 - 40354
Production Date	14/04/2016
Expiration Date	EXP 14/04/2018

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	0.887

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

This document being issued electronically does not bear a signature

COA 7515783	Version : 03	Date of issuing : November 28 <sup>th</sup> 2011
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<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 29-Apr-2016

UK32S11609110-1-1

This is to certify that Bradford 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  
Hightown  
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:	1002733
Customer Reference Number:	P026412
Product Description:	JD DE 900ML BOTTLES 25-45kGy
Validation Reference:	4.1756
Quantity Received:	703
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	699 X BATCH NO: FMP 16105 40354 + 4 SAMPLES THURS 21ST APR 2016 13 PLTS LOT 2

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### Irradiation Data

Date and Time of Irradiation:	29-Apr-2016 14:06
Reference Dose Range kGy:	36.0 - 39.1
Calculated Minimum Dose kGy:	27.0
Calculated Maximum Dose kGy:	42.4

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Irradiation Release Authorised By Synergy Health plc

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Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

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



# 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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www.wickhamlabs.co.uk

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

**Date Received:** 09 May 2016  
**Date Tested:** 11 May 2016  
**Date Test Completed:** 11 May 2016  
**Purchase Order:** 26542

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0028849/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL  
**Date Received:** 09/05/2016  
**Test Article:** Clearklens DE  
**Sample Code:** FMP16105 40354  
**Batch Ref:** 7534  
**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	79 %
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 8.0 2.6.14, USP 39 <85> & JPXVI 4.01
Product Standard Data Sheet	FG047/psd	FM01

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

Date: 12 May 2016 15:44:55

Mr K.A. Barker  
Business Manager – Projects



# 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:** 09 May 2016  
**Date Tested:** 19 May 2016  
**Date Test Completed:** 02 Jun 2016  
**Purchase Order:** 26542

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0028849/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 09/05/2016  
**Test Article:** Clearklens DE  
**Sample Code:** FMP16105 40354  
**Batch Ref:** 7534  
**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

See deviation report PHM 2016 109.

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.

Date: 03 Jun 2016 12:28:38

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology