

**Tel. +31 (0)30 247 6427**

## CERTIFICATE OF ANALYSIS

Date: 9.04.2015

Product Name	CLEARKLENS DE VH29
Product Code	7515783
Batch Number	FMP 15047, 37691
Production Date	23/02/2015
Expiration Date	23/02/2017

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 Colorless Liquid
Specific Gravity (20°C)	JDM004	0.880	0.888	0.883

On behalf of Diversey site Quality Manager	Name :	<i>Barry Egle, Alameda</i>
	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: 11-Mar-2015

UK32S11339023-1-1

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

EN ISO 11137-1:2006 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

## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1002733
Customer Reference Number:	P023887
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 B/N FMP15047 37691 + 4 SAMPLES THUR 26 FEB 2015 13 PLTS LOT 1

## Irradiation Data

Date and Time of Irradiation:	10-Mar-2015 14:26
Reference Dose Range kGy:	37.5 - 38.4
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	41.6

Irradiation Release Authorised By Synergy Health plc

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

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

**Date Received:** 16 Mar 2015  
**Date Tested:** 19 Mar 2015  
**Date Test Completed:** 02 Apr 2015  
**Purchase Order:** 24004

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0021676/2  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 16/03/2015  
**Test Article:** ClearKlens DE Block 2  
**Sample Code:** 6285  
**Batch Ref:** FMP15047 37691  
**Qty Received:** 20 x 900mL Bottles

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
Product Standard Data Sheet	FG047/psd	FM03

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 07 Apr 2015 15:33:35

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0021676

Certificate of Analysis - OSMM

Print Number: P0026510

Page 1 of 1

ISO  
17025

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited,  
Registered Office: Hoeford Point, Barwell Lane, Gosport, Hampshire

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

**Date Received:** 16 Mar 2015  
**Date Tested:** 17 Mar 2015  
**Date Test Completed:** 17 Mar 2015  
**Purchase Order:** 24004

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0021676/1  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP  
**Date Received:** 16/03/2015  
**Test Article:** ClearKlens DE Block 2  
**Sample Code:** 6285  
**Batch Ref:** FMP15047 37691  
**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	146 %
Dilution Tested	MM110/04	1/50
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	FG047/psd	FM01

### Comments

Test carried out according to current Pharmacopoeias.

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



Date: 19 Mar 2015 12:56:22

Mr K.A. Barker  
Business Manager - Microbiology

Consignment: 0021676

Certificate of Analysis - OSMM

Print Number: P0026208 Page 1 of 1

**ISO 17025 GLP GMP FDA**

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