



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 12/12/11

Product Name	CLEARKLENS DE VH29
Product Code	6069643
Batch Number	W031005
Production Date	11/2011
Expiration Date	11/2013

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	0.885

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

This document being issued electronically does not bear a signature

COA 6069643	Version : 03	Date of issuing : November 28 <sup>th</sup> 2011
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## 0512110 00

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Bradford · West Yorkshire  
BD4 6SE · United Kingdom  
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Facsimile: +44 (0)1274 686061  
Email: [assistance@isotron.com](mailto:assistance@isotron.com)  
Website: [www.isotron.com](http://www.isotron.com)

Cust. Ref: P017811  
Date Rec'd 24/11/11  
Date: 2/12/11

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE00000121 B211120017	JD DE 900ML BOTTLES 25-45kGy	599	B/No.W031005 CUSTOMER B/No.3039 ACTUAL DOSE...35.4 - 37.0...kGy
B2FLE0010999 B211120017	SAMPLES	5	CUSTOMER BATCH/CODE No.s AS ORDER No.P017811 DATED 23/11/2011
Despatch Text:  12PLTS			
Total		604	Last Page 1 of 1
		All in accordance with current Technical Agreement	
		This is to certify that the above items have been irradiated as specified above	
		Authorising Signature: 	
		For and on behalf of ISOTRON LIMITED	

## CERTIFICATE OF ANALYSIS

Mr J Jackson  
 Flexible Medical Packaging Limited  
 Unit 8  
 Hightown  
 White Cross Industrial Estate  
 Lancaster  
 LA1 4XS

**Date Received:** 12 Dec 11  
**Date Tested:** 15 Dec 11  
**Date Completed:** 15 Dec 11  
**Purchase Order:** 17885

**Test Article:** ClearKlens DE Block 1  
**Sample Code:** 3039  
**Batch Ref:** WO31005  
**Qty Received:** 1 x 900mL Bottle  
**Laboratory Reference:** 0002989/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.25 EU/mL
Spiked Recovery	MM110/01	85 %
Dilution Tested	MM110/04	1/50
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	MM110/05	FM01

### External Comments

Test carried out according to current Pharmacopoeias.

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



Date: 16 Dec 11 14:13:03

Mrs S.L. Wood, BSc (Hons), CBiol, MSB  
 Senior Laboratory Manager - Pharmaceutical Microbiology

**Consignment:** 0002989  
 Lancaster

Certificate of Analysis - OSMM

Print Number

P0000919

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**Wickham Laboratories**  
contract analytical services

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## CERTIFICATE OF ANALYSIS

Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

Date Received: 12 Dec 11  
Date Tested: 16 Dec 11  
Date Completed: 30 Dec 11  
Purchase Order: 17885

Test Article: ClearKlens DI; Block 1  
Sample Code: 3039 2013/11  
Batch Ref: WO31005  
Qty Received: 20 x 900mL Bottles  
Laboratory Reference: 0002989/1  
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

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
Product Standard Data Sheet	MM107/03	FM03
Volume Tested	MM107/05	20 x 50 mL

### External Comments

Test carried out according to current Pharmacopoeias.

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

Date: 03 Jan 12 16:20:09

Mrs S.L. Wood, BSc (Hons), CBiol, MSB  
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0002989  
Lancaster

Certificate of Analysis - OSMM

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