

#### Contact address:

JohnsonDiversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands Tel. +31 (0)30 247 6427

## **CERTIFICATE OF ANALYSIS**

Date:24/9/10

Product Name	CLEARKLENS DE VH29
Product Code	6069643
Batch Number	NO 28637
<b>Production Date</b>	09/2010
Expiry Date	09/2012

This is to certify that the above batch of product has been produced conforming to the manufacturing dossier from JohnsonDiversey in which the formula and processing instructions are defined and has been tested with the following Quality Control specification for the product.

Test	Test Method	Limits	Results ,
Appearance	Visual	Clear Liquid	Clear 1,8010
Specific Gravity (20°C)	JDM004	0.880 - 0.888	0.882

Signature / name C Alsove
On behalf of Manufacturing Location







# CERTIFICATE OF IRRADIATION Number: B

0461727 00

FLECO1

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: PC

Date:

P015885 16/09/10

21/09/10



#### **Isotron Limited**

Page

Roydsdale Way · Euroway Trading Estate

1

Bradford · West Yorkshire
BD4 6SE · United Kingdom
Telephone: +44 (0)1274 686011
Facsimile: +44 (0)1274 686061
Email: assistance@isotron.com

Website: www.isotron.com

Date: 21/09/	/10		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
82FLE0010121 B210090499	JD DE 900ML BOTTLES 25-45kGy	338	124 x W028636 214 x <mark>W028637</mark> B/No.1984 ACTUAL DOSE37.2 - 38.9kGy
B2FLE0010999 B210090499	SAMPLES	10	CUSTOMERS BATCH/CODE NO'S AS ORDER NO P015885 DATED 15.09.2010
	-		
	Total	348	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



Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire PO17 5EU England Telephone: +44(0)1329 832511

+44(0)1329 834262

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

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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** 

27-Sep-10

**Date Tested** 

28-Sep-10

**Date Completed** 

28-Sep-10

Purchase Order No.

15943

**Test Article** 

: ClearKLens

Sample Code

**Batch Reference** 

: W028637

Laboratory Reference

: LR-00985387

Article Quantity: 1x900mLs

Test Required

: LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. Ph Eur and USP.

Test		Method	Result	
Bacterial Endotoxin by LAL, Kinetic QCL Test	*	MM110	<0.2500 EU/mL	
Dilution	*	MM110/01	1/50	
Spiked Recoveries	*	MM110/02	Valid 76%	
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL	
Product Standard Data Sheet	*	MQ002/01	FM01	

Test carried out according to current Pharmacopoeias.

 $\operatorname{GLP}$ 

Compliant Laboratory

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Date OI Out Lov

Laboratory Manager - Pharmaceutical Microbiology

CN\00154711

Certificate of Analysis - OSMM

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Sample Booking Number: Flexible Medical Packaging Limited

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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

27-Sep-10

**Date Tested** 

06-Oct-10

**Date Completed** 

20-Oct-10

Purchase Order No.

15943

Test Article

: Clearklens DE Block 1

Sample Code

**Batch Reference** 

: WO28637

Laboratory Reference

: LR-00985386

Article Quantity : 20x900mLs+spare

**Test Required** 

: Sterility Method I: Membrane Filtration by Steritest. Ph Eur and USP.

Test		Method	Result
Sterility Test by Membrane Filtration (Steritest) Method	*	MM107	Pass
Growth in Tryptone Soya Broth at 22°C after 14 days	*	MM107/01	0/1
Growth in Fluid Thioglycollate at 32°C after 14 days	*	MM107/02	0/1
Product Standard Data Sheet	*	MQ002/01	FM03

Day Book Ref: 000023 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

 ${f GLP}$ 

Compliant Laboratory

Mr K A Barker, CBiol., MSB **Business Manager** 

Date 26 Oct 2010

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number: Flexible Medical Packaging Limited

CN\00154711

Certificate of Analysis - OSMM

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