

#### Contact address:

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

# CERTIFICATE OF ANALYSIS

Date: 94/10

Product Name	CLEARKLENS DE VH29		
Product Code	7515783		
Batch Number	WO 27911		
Production Date	04/2010		
Expiry Date	CVH/2017		

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 1/201d	
Specific Gravity (20°C)	JDM004	0.880 - 0.888	0.882	

Signature / name C Pascoe Caroline Poscoe 12/4/10
On behalf of Manufacturing Location





# CERTIFICATE OF IRRADIATION Number: B

0442873 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd Date:

P015270 1/04/10

7/04/10



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### **Isotron Limited**

Roydsdale Way · Euroway Trading Estate

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: 7/04/	Date: 7/04/10			
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS	
B2FLE0010081 B210040065	JD JPA BOTTLES 25-45kGy DE .	95	B/No.W027911 - P/REF.7515783 ACTUAL DOSE38.5 - 39.1kGy	
B2FLE0010999 B210040065	SAMPLES  Despatch Text:	5	CUSTOMERS BATCH/CODE No.s AS ORDER No.P015270 DATED 31/3/10	
	2PLTS			
	Total	100	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 LIMHTED



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

Fax: +44(0)1329 834262

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

# CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received : 13-Apr-10

Date Tested : 19-Apr-10

Date Completed : 19-Apr-10

Purchase Order No. : 15305

**Test Article** 

: Clearklens DE Block 2

Sample Code

: Works Order 27911

**Batch Reference** 

: 1599

Laboratory Reference

: LR-00950243

Article Quantity: 1x900mL

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 88%
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL
Product Standard Data Sheet	*	MQ002/01	FM01

Test carried out according to current Pharmacopoeias.

Date 23 April 20

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

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00149097

Certificate of Analysis - OSMM

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GLP

Compliant Laboratory

Flexible Medical Packaging Limited

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## CERTIFICATE OF ANALYSIS

Mr J Jackson

Date Received

13-Apr-10

Flexible Medical Packaging Limited

Date Tested : 15-Apr-10

Unit 8, Hightown

Date Completed : 29-Apr-10

White Cross Industrial Estate Lancaster LA1 4XS

Purchase Order No. : 15305

**Test Article** 

: Clearklens DE Block 2

Sample Code

: Works Order 27911

**Batch Reference** 

: 1599

Laboratory Reference

: LR-00950242

Article Quantity: 20x900mL

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: 800026 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Sun vad

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

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00149097

Certificate of Analysis - OSMM

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