

#### Contact address:

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

## **CERTIFICATE OF ANALYSIS**

Date: 9/4/10

Product Name	CLEARKLENS DE VH29	
Product Code	6069643	
Batch Number	WO 27555	
Production Date	03/2010	
Expiry Date	03/2012	

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 liguid
Specific Gravity (20°C)	JDM004	0.880 - 0.888	0.883

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





# CERTIFICATE OF IRRADIATION Number: B

0442872 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

P015270 Cust. Ref: 1/04/10 Date Rec'd Date:

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 assistance@isotron.com Email:

Website: www.isotron.com

Date: 771347			
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B210040066	JD DE 900ML BOTTLES 25-45kGy	589	B/No.W027555 - CUSTOMER B/No.1599  ACTUAL DOSE37.6 - 39.6kGy
B2FLE0010999 B210040066	SAMPLES	7	CUSTOMERS BATCH/CODE No.s AS ORDER
			No .P015270 DATED 31/3/10
	December Tanks		
	Despatch Text: 11PLTS		
	Total	596	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

### 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.

15306

**Test Article** 

: Clearklens DE Block 1

Sample Code

: Works Order 27555

**Batch Reference** 

: 1599

Laboratory Reference : LR-00950263

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 80%
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL
Product Standard Data Sheet	*	MQ002/01	FM01

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

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

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00149099

Certificate of Analysis - OSMM

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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** 

13-Apr-10

**Date Tested** 

15-Apr-10

**Date Completed** 

29-Apr-10

Purchase Order No.

15306

**Test Article** 

: Clearklens DE Block 1

Sample Code

: Works Order 27555

**Batch Reference** 

: 1599

Laboratory Reference

: LR-00950262

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: 800027 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

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

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00149099

Certificate of Analysis - OSMM

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Date 05 May 2010