



**CERTIFICATE OF ANALYSIS**

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W025751
PRODUCTION DATE	02/2009
EXPIRY DATE	02/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.876 – 0.896	0.884

Date:.....05/03/09.....

QA Manager:.....*[Signature]*.....

QA:.....*E. Gausman*.....

JD Approval:.....*[Signature]*.....

*This document has been produced on behalf of JohnsonDiversey by authorised personnel.*

FLE001

Page 1

Flexible Medical Packaging Ltd  
 Unit 8  
 White Cross Industrial Estate  
 Hightown  
 Lancaster



**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

LA1 4XS

Cust. Ref: P013746  
 Date Rec'd 19/02/09  
 Date: 24/02/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209020549	JD DE 900ML BOTTLES 25-45kGy	683	172 X B/No.W025362 - CB/No.FC470 340 X B/No.W025197 - CB/No.FC401 171 X B/No.W025751 - CB/No.FC470  ACTUAL....37.6 - 39.3....kGy DOSE
B2FLE0010999 B209020549	SAMPLES	7	CUSTOMERS BATCH/CODE No.s AS ORDER No.P013746 DATED 18/2/09
Total		690	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: *C. Drake*

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** : 06-Mar-09  
**Date Tested** : 11-Mar-09  
**Date Completed** : 13-Mar-09  
**Purchase Order No.** : -

**Test Article** : Clearklens DE Block 1  
**Sample Code** :  
**Batch Reference** : WO25751  
**Laboratory Reference** : LR-00836322 **Article Quantity** : 1 x 900mLs  
**Test Required** : LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. BP, Ph Eur and USP.

Test	Method	Result
Bacterial Endotoxin by LAL, Kinetic QCL Test	* MM110	<0.25 EU/mL
Dilution	* MM110/01	1/50
Spiked Recoveries	* MM110/02	108% Valid
Endotoxin Spike Level	* MM110/09	0.5 EU/mL
Product Standard Data Sheet	* MQ002/01	FM01

This sample was tested at a 1/50 dilution and spiked with endotoxin to check for interference.  
Test carried out according to current Pharmacopoeias.



*W.A.B.*

Date 19 Mar 2009

K.A.Barker, C.Biol, M.I. Biol.,  
Business Manager - Microbiology

**Sample Booking Number:** CN\00132934  
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

Page 1 of 1

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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** : 06-Mar-09  
**Date Tested** : 10-Mar-09  
**Date Completed** : 24-Mar-09  
**Purchase Order No.** : -

**Test Article** : Clearklens DE Block 1  
**Sample Code** :  
**Batch Reference** : WO25751  
**Laboratory Reference** : LR-00836321 **Article Quantity** : 23 x 900mLs  
**Test Required** : Sterility Method I: Membrane Filtration by Steritest. BP, 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: 380037  
Volume Tested: 20x50mL  
Test carried out according to current Pharmacopoeias.



*W.A.B.*

Date 27 Mar 2009

K.A.Barker, C.Biol, M.I. Biol.,  
Business Manager - Microbiology

**Sample Booking Number:** CN\00132934  
Flexible Medical Packaging Limited

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Page 1 of 1

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