



### CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W026147
PRODUCTION DATE	05 / 2009
EXPIRY DATE	05 / 2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.876 – 0.896	0.880

Date: 23/05/09

QA Manager: [Signature]

QA: [Signature]

JD Approval: [Signature]

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

FLE001

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



**Isotron Limited**

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Facsimile: +44 (0)1274 686061  
Email: assistance@isotron.com  
Website: www.isotron.com

LA1 4XS

Cust. Ref: P014107  
Date Rec'd 22/05/09  
Date: 28/05/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209050566	JD DE 900ML BOTTLES 25-45kGy	699	B/No.W026147 - CUSTOMER B/No.844  ACTUAL....38.1 - 41.2....kGy DOSE
B2FLE0010999 B209050566	SAMPLES	2	          CUSTOMERS BATCH/CODE No.s AS ORDER No.P014107 DATED 21/5/09
Total		701	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 : 01-Jun-09  
Date Tested : 15-Jun-09  
Date Completed : 29-Jun-09  
Purchase Order No. : PO14122

Test Article : Clearklens DE Block 1  
Sample Code : Works Order No. 26147  
Batch Reference : 844  
Laboratory Reference : LR-00860583 Article Quantity : 20  
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: 484045  
Volume Tested: 20 x 50 mL  
Test carried out according to current Pharmacopoeias.

**GLP**

Compliant  
Laboratory

*W.B.*

Date 02 July 2009

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

Sample Booking Number: CN\00136352  
Flexible Medical Packaging Limited

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** : 01-Jun-09  
**Date Tested** : 08-Jun-09  
**Date Completed** : 08-Jun-09  
**Purchase Order No.** : PO14122

**Test Article** : Clearklens DE Block 1  
**Sample Code** : Works Order No. 26147  
**Batch Reference** : 844  
**Laboratory Reference** : LR-00860584 **Article Quantity** : 1  
**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	<0.2500 EU/mL
Dilution	*	MM110/01	1/50
Spiked Recoveries	*	MM110/02	Valid 105%
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.

**GLP**

Compliant  
Laboratory

**Date** 11 June 2009

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

**Sample Booking Number:** CN\00136352  
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

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