



## CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W026703
PRODUCTION DATE	09/2009
EXPIRY DATE	09/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	Clear colourless Liquid
Density (20°C)	GM 0110 01	0.876 – 0.896	0.886

Date: 02/10/09

QA Manager: [Signature]

QA: E. G. [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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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: P014556  
Date Rec'd 17/09/09  
Date: 23/09/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209090429	JD DE 900ML BOTTLES 25-45kGy	174	B/No.W026703 - CUSTOMER B/No.1248  ACTUAL....38.2 - 39.6....kGy DOSE
Total		174	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: *J. Coffey*

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 : 05-Oct-09  
Date Tested : 08-Oct-09  
Date Completed : 08-Oct-09  
Purchase Order No. : PO14631

Test Article : Clearklens DE Block 1

Sample Code : Works Order 26703

Batch Reference : 1248

Laboratory Reference : LR-00893663

Article Quantity : 1 Bottle

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
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.

*MR*

Date 19 Oct 2009

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

**GLP**  
Compliant  
Laboratory

Sample Booking Number: CN\00141414

Certificate of Analysis - OSMM

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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 : 05-Oct-09  
Date Tested : 16-Oct-09  
Date Completed : 30-Oct-09  
Purchase Order No. : PO14631

Test Article : Clearklens DE Block 1

Sample Code : Works Order 26703

Batch Reference : 1248

Laboratory Reference : LR-00893662

Article Quantity : 20 Bottles

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: 649025

Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

*Sue Wood*

Mrs S L Wood BSc, C.Biol., MSB

Laboratory Manager - Pharmaceutical Microbiology

K.A.Barker, C.Biol, M.I. Biol.,

Business Manager - Microbiology

Date 06 Nov 2009

GLP

Compliant  
Laboratory

Sample Booking Number: CN\00141414

Flexible Medical Packaging Limited

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