



## CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W026429
PRODUCTION DATE	08/2009
EXPIRY DATE	08/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.876 – 0.896	0.885

Date: 07/09/09

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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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: P014458  
Date Rec'd 25/08/09  
Date: 2/09/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209080564	JD DE 900ML BOTTLES 25-45kGy	700	BATCH NO: W026429-CUST B/NO: 1024  ACTUAL....36.2 - 39.1....kGy DOSE
B2FLE0010999 B209080564	SAMPLES	2	CUSTOMERS BATCH/CODE NO'S AS ORDER MO P0 14458 DATED 01.09.09
Total		702	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** : 07-Sep-09  
**Date Tested** : 10-Sep-09  
**Date Completed** : 24-Sep-09  
**Purchase Order No.** : P014503

**Test Article** : ClearKlens DE Block 1

**Sample Code** :

**Batch Reference** : WO26429

**Laboratory Reference** : LR-00886368

**Article Quantity** : 20 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	FMO3

Day Book Ref: 649005

Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

*WR*

**Date** 30 Sep 2009

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

**GLP**  
Compliant  
Laboratory

**Sample Booking Number:** CN\00140316  
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** : 07-Sep-09  
**Date Tested** : 08-Sep-09  
**Date Completed** : 08-Sep-09  
**Purchase Order No.** : P014503

**Test Article** : ClearKlens DE Block 1

**Sample Code** :

**Batch Reference** : W026429

**Laboratory Reference** : LR-00886367

**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	<0.2500 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.

*W.A.B.*

Date 14 Sep 2009

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

**GLP**

Compliant  
Laboratory

**Sample Booking Number:** CN00140316

Certificate of Analysis - OSMM

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