

**CERTIFICATE OF IRRADIATION** Number: **B** 0381290 00

FLE001

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Flexible Medical Packaging Ltd  
 Unit B  
 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

LAI 4XS

Cust. Ref: P013083  
 Date Rec'd 28/08/08  
 Date: 2/09/08

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B208090006	JD DE 900ML BOTTLES 25-45kGy	172	B/No.WO24940 CUSTOMER B/No.29599  ACTUAL....36.6 - 37.5....kGy DOSE
B2FLE0010999 B208090006	SAMPLES	4	CUSTOMERS BATCH/CODE No.s AS ORDER No.P013083 DATED 27/8/08
Total		176	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. Drace*

For and on behalf of ISOTRON LIMITED



## CERTIFICATE OF ANALYSIS

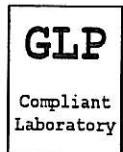
Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8, Hightown  
White Cross Industrial Estate  
Lancaster LA1 4XS

**Date Received** : 10-Sep-08  
**Date Tested** : 19-Sep-08  
**Date Completed** : 03-Oct-08  
**Purchase Order No.** : P013130

**Test Article** : Clearklens DE  
**Sample Code** :  
**Batch Reference** : WO24940  
**Laboratory Reference** : LR-00788061 **Article Quantity** : 23 x 900mL  
**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: 226048  
Volume Tested: 20 X 50mL  
Test carried out according to current Pharmacopoeias.  
3 boxes arrived on 10/09/08, 1 further box arrived on 15/09/08.



*W.B.*

Date 07 Oct 2008

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



**CERTIFICATE OF ANALYSIS**

Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8, Hightown  
White Cross Industrial Estate  
Lancaster LA1 4XS

**Date Received** : 10-Sep-08  
**Date Tested** : 12-Sep-08  
**Date Completed** : 12-Sep-08  
**Purchase Order No.** : P013130

**Test Article** : Clearklens DE  
**Sample Code** :  
**Batch Reference** : WO24940  
**Laboratory Reference** : LR-00788062 **Article Quantity** : 1 x 900mL  
**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	95% Valid
Endotoxin Spike Level	* MM110/09	0.5 EU/mL

This sample was tested at a 1/50 dilution and spiked with endotoxin to check for interference.  
Test carried out according to current Pharmacopoeias.  
Product Standard Data Sheet: FM01

*S L Wood*

Mrs S L Wood, BSc, CBiol, MIBiol  
Laboratory Manager - Pharmaceutical Microbiology

Date 18 Sep 2008



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

**Sample Booking Number:** CN00126077  
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

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JohnsonDiversey  
Clean is just the beginning



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W024940
PRODUCTION DATE	08/2008
EXPIRY DATE	08/2010

TEST	METHOD	LIMITS	RESULTS
Appearance		Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.876 - 0.896	0.882

Date: 08/09/08

QA Manager: [Signature]

QA: [Signature]

JD Approval: [Signature] 8/9/08

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

Issue no. 4  
Issued by W. Ashton  
Issue date 07.04.2006