



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W026305
PRODUCTION DATE	06/2009
EXPIRY DATE	06/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.876 - 0.896	0.878

Date: 06/07/09  
 QA Manager: [Signature]  
 QA: K. Gough  
 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**

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: P014214  
 Date Rec'd 25/06/09  
 Date: 6/07/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209070003	JD DE 900ML BOTTLES 25-45kGy	706	BATCH NO: W026305 - CUST NO: 902  ACTUAL....37.0 - 38.0....kGY DOSE  CUSTOMERS BATCH/CODE NO'S AS ORDER NO P014214 DATED 24.06.09
B2FLE0010999 B209070003	SAMPLES	4	
Total		710	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 : 09-Jul-09  
Date Tested : 15-Jul-09  
Date Completed : 15-Jul-09  
Purchase Order No. : 014263

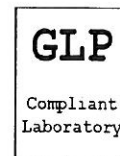
Test Article : Clearklens DE Block 1  
Sample Code : Works Order No. 26305  
Batch Reference : 902  
Laboratory Reference : LR-00870993 Article Quantity : 1 Bottle  
Test Required : LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. BP, Ph Eur and USP.

Test	Method	Result
Bacterial Endotoxin by LAL, Kinetic QCL Test *	MM110	<0.25 EU/mL
Dilution *	MM110/01	1/50
Spiked Recoveries *	MM110/02	90% 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.

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

Date *22 July 2009*



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

Sample Booking Number: CN00137974  
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** : 09-Jul-09  
**Date Tested** : 17-Jul-09  
**Date Completed** : 31-Jul-09  
**Purchase Order No.** : 014263

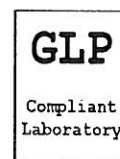
**Test Article** : Clearklens DE Block 1  
**Sample Code** : Works Order No. 26305  
**Batch Reference** : 902  
**Laboratory Reference** : LR-00870992 **Article Quantity** : 20 Bottles  
**Test Required** : Sterility Method I: Membrane Filtration by Steritest. BP, Ph Eur and USP.

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: 574021  
Volume Tested: 10 x 50mL  
Test carried out according to current Pharmacopoeias.

*Suz Wood*  
Mrs S.L. Wood, BSc, CBiol., MIBiol  
Laboratory Manager - Clinical Microbiology

Date 07 Aug 2009



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

**Sample Booking Number:** CN\00137974  
Flexible Medical Packaging Limited

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