




**CERTIFICATE OF ANALYSIS**

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W026793
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:..........

QA:.....E. Gavan.....

JD Approval:..........

*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: P014534  
 Date Rec'd 15/09/09  
 Date: 22/09/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209090376	JD DE 900ML BOTTLES 25-45kGy	877	B/No.W026793 - CUSTOMER B/No.1134  ACTUAL....35.8 - 37.5....kGy DOSE
B2FLE0010999 B209090376	SAMPLES	5	CUSTOMERS BATCH/CODE No.s AS ORDER No.P014534 DATED 11/9/09
Total		882	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.** : PO14632

**Test Article** : Clearklens DE Block 1  
**Sample Code** : Works Order 26793  
**Batch Reference** : 1134  
**Laboratory Reference** : LR-00893665 **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.

Date 19 Oct 2009

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



**Sample Booking Number:** CN00141415  
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

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## CERTIFICATE OF ANALYSIS

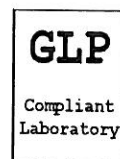
Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8, Hightown  
White Cross Industrial Estate  
Lancaster LA1 4XS

**Date Received** : 05-Oct-09  
**Date Tested** : 13-Oct-09  
**Date Completed** : 27-Oct-09  
**Purchase Order No.** : PO14632

**Test Article** : Clearklens DE Block 1  
**Sample Code** : Works Order 26793  
**Batch Reference** : 1134  
**Laboratory Reference** : LR-00893664 **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 50 mL  
Test carried out according to current Pharmacopoeias.



Mr K A Barker, CBiol., MSB  
Business Manager

*WAB*

Date 29 Oct 2009

Mrs S.L. Wood, B.Sc. (Hons), C.Biol., MSB.,  
Laboratory Manager - Pharmaceutical Microbiology

**Sample Booking Number:** CN00141415  
Flexible Medical Packaging Limited

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