



## CERTIFICATE OF ANALYSIS

|                 |               |
|-----------------|---------------|
| PRODUCT NAME    | CLEARKLENS DE |
| PRODUCT CODE    | 6069643       |
| BATCH NUMBER    | W026274       |
| 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           | 0.882                   |

Date:.....11/08/09.....  
 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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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: P014365  
Date Rec'd 30/07/09  
Date: 6/08/09

| ITEM CODE<br>ISOTRON BATCH | ITEM SPECIFICATION           | QTY | ADDITIONAL DETAILS                                                                                     |
|----------------------------|------------------------------|-----|--------------------------------------------------------------------------------------------------------|
| B2FLE0010121<br>B209080092 | JD DE 900ML BOTTLES 25-45kGy | 703 | B/No.W026274 - CUSTOMER B/No.933<br><br>ACTUAL....36.8 - 38.1....kGy<br>DOSE                           |
| B2FLE0010999<br>B209080092 | SAMPLES                      | 2   | <br><br><br><br><br><br><br><br><br><br>CUSTOMERS BATCH/CODE No.s AS ORDER<br>No.P014365 DATED 29/7/09 |
| Total                      |                              | 705 | 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** : 12-Aug-09  
**Date Tested** : 20-Aug-09  
**Date Completed** : 03-Sep-09  
**Purchase Order No.** : PO14388

**Test Article** : Clearklens DE

**Sample Code** :

**Batch Reference** : WO26274

**Laboratory Reference** : LR-00880207

**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: 574038

Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

**GLP**

Compliant  
Laboratory

*WJR*

Date 14 Sep 2009

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

**Sample Booking Number:** CN\00139421

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 : 12-Aug-09  
Date Tested : 18-Aug-09  
Date Completed : 18-Aug-09  
Purchase Order No. : PO14388

Test Article : Clearklens DE  
Sample Code :  
Batch Reference : WO26274  
Laboratory Reference : LR-00880208 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.

GLP

Compliant  
Laboratory

*W.A. Barker*

Date 26 Aug 2009

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

Sample Booking Number: CN00139421

Certificate of Analysis - OSMM

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