

Contact address:

JohnsonDiversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands Tel. +31 (0)30 247 6427

## **CERTIFICATE OF ANALYSIS**

Date: 9. 07.2010

| Product Name    | CLEARKLENS DE VH29 |  |  |
|-----------------|--------------------|--|--|
| Product Code    | 6069643            |  |  |
| Batch Number    | NO 28266           |  |  |
| Production Date | © 2012 2010 10C    |  |  |
| Expiry Date     | 2012106            |  |  |

This is to certify that the above batch of product has been produced conforming to the manufacturing dossier from JohnsonDiversey in which the formula and processing instructions are defined and has been tested with the following Quality Control specification for the product.

| Test                    | Test Method | Limits        | Results       |
|-------------------------|-------------|---------------|---------------|
| Appearance              | Visual      | Clear Liquid  | Class Lightid |
| Specific Gravity (20°C) | JDM004      | 0.880 - 0.888 | 0.886         |

Signature / name Ago Figill
On behalf of Manufacturing Location







# CERTIFICATE OF IRRADIATION Number: B

Page

0452528 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

P015561 Cust. Ref: Date Rec'd 28/06/10 Date:

5/07/10



# **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

| Date: 5/07.                | /10                          |     |  |
|----------------------------|------------------------------|-----|--|
| ITEM CODE<br>ISOTRON BATCH | ITEM SPECIFICATION           | QTY | ADDITIONAL DETAILS   |
| B2FLE0010121<br>B210070083 | JD DE 900ML BOTTLES 25-45kGy | 528 |  |
|                            |                              |     | ACTUAL DOSE35.4 - 36.0kGy                                      |
| B2FLE0010999<br>B210070083 | SAMPLES                      | 5   | CUSTOMERS BATCH/CODE No.s AS ORDER<br>No.P015561 DATED 25/6/10 |
|                            |                              |     |  |
|                            |                              |     |  |
|                            |                              |     |  |
|                            |                              |     |  |
|                            |                              |     |  |
|                            |                              |     |  |
|                            |                              |     |  |
|                            |                              |     |  |
|                            | Despatch Text:               |     |  |
|                            | 10PLTS                       |     |  |
|                            | Total                        | 533 | Last Page 1 of 1   |
|                            | , , ,                        | 555 | 230 t 1 age 1 VI 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



Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire PO17 5EU England Telephone: +44(0)1329 832511

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mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

#### CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

**Date Received** 12-Jul-10

**Date Tested** 13-Jul-10

**Date Completed** 13-Jul-10

Purchase Order No. PO15625

**Test Article** 

: ClearKlens DE Block 1

Sample Code

**Batch Reference** 

: WO28266

Laboratory Reference

: LR-00973828

Article Quantity: 1x900mL Bottle

**Test Required** 

: LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. 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 67%     |
| Endotoxin Spike Level                        | * | MM110/09 | 0.5 EU/mL     |
| Product Standard Data Sheet                  | * | MQ002/01 | FM01          |

Test carried out according to current Pharmacopoeias.

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00152449

Certificate of Analysis - OSMM

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GLP

Compliant Laboratory

Flexible Medical Packaging Limited

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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-Jul-10

**Date Tested** 

15-Jul-10

**Date Completed** 

29-Jul-10

Purchase Order No.

PO15625

**Test Article** 

: ClearKlens DE Block 1

Sample Code

**Batch Reference** 

: WO28266

Laboratory Reference

: LR-00973827

Article Quantity : 20x900mL Bottle

Test Required

: Sterility Method I: Membrane Filtration by Steritest. Ph Eur and USP.

| Test  |   | Method   | Result |
|---|---|----------|--------|
| Sterility Test by Membrane Filtration (Steritest)<br>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: 900026 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00152449

Certificate of Analysis - OSMM

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