

# CERTIFICATE OF IRRADIATION

Number: **B** 0512914 00

FLE001

Page 1

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: P017861  
 Date Rec'd 1/12/11  
 Date: 5/12/11

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
E2FLE0010134 B211120195	C/SINALD BLK BOTT/CAPS/BAGS 25-40kg	11	B/Nb. W031298 - W1031299.  CUSTOMER BATCH/CODE No.s AS ORDER No. P017861 DATED 30/11/11
Despatch Text:  2PLTS		Total	11 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



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 4/1/12

Product Name	CLEARKLENS CLEANSINALD SC VH9
Product Code	7516429
Batch Number	W031299
Production Date	01/2012
Expiration Date	01/2014

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear	Slightly Yellow	Clear slightly yellow liquid
pH (100% 20°C)	JDM001	12.0	13.0	12.8
Specific Gravity (20°C)	JDM004	1.040	1.060	1.041

On behalf of Diversey site Quality Manager	Name :	<i>Caroline Boer</i>
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

COA 7516429	Version : 03	Date of issuing : November 28 <sup>th</sup> 2011
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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:** 06 Jan 12  
**Date Tested:** 12 Jan 12  
**Date Completed:** 26 Jan 12  
**Purchase Order:** PO17975

**Test Article:** Clearklens Cleansinald SC Block 1  
**Sample Code:** -  
**Batch Ref:** WO31299  
**Qty Received:** 20 x 25mL  
**Laboratory Reference:** 0003161/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Product Standard Data Sheet	MM107/03	FM06
Volume Tested	MM107/05	20 x 25 mL

**External Comments**

Test carried out according to current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name is shown below.

Date: 27 Jan 12 15:24:21

Mr K.A. Barker, CBiol, MSB  
Business Manager - Microbiology

Consignment: 0003161  
Lancaster

Certificate of Analysis - OSMM

Print Number

P0001341

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