



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 14/6/13

Product Name	CLEARKLENS CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FMP13165 34153
Production Date	06/2013
Expiration Date	06/2015

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 Liquid	Clear slightly yellow liquid
pH (100% 20°C)	JDM001	12.0	13.0	13.0
Specific Gravity (20°C)	JDM004	1.040	1.060	1.049

On behalf of Diversey site Quality Manager	Name :	<i>Chloe Hlaing</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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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 30-May-2013

UK32S11023260-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

ISO 11137:2006 Sterilisation of Health Care Products  
 ISO 9001:2008 Quality Management System  
 ISO 13485:2012 Quality System - Medical Devices

Flexible Medical Packaging Ltd  
 Unit 8, White Cross Ind Estate  
 Hightown  
 Lancaster  
 Lancashire LA1 4XS  
 UNITED KINGDOM

All in accordance with current Technical Agreement

## Order Information

Customer Reference Number:	P020493
Product Description:	C/SINALD BLK BOTT/CAPS/BAGS 25-40kGy
Validation Reference:	4.0616
Quantity Received:	11
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	B/No.WO34150 , 2 PLTS LOT 2 THURS 23.5.13
Shop Order Number:	S11023260-1-1
Synergy Health Sales Part Reference:	1002719

## Irradiation Data

Date and Time of Irradiation:	30-May-2013 10:46
Reference Dose Range kGy:	35.0 - 36.5
Calculated Minimum Dose kGy:	29.0
Calculated Maximum Dose kGy:	37.3

Items Irradiated under WO34150 will be used in finished product batch code  
 FMP13165 34153

20-06-13 L. Gough

Irradiation Release Authorised By Synergy Health plc

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



**Wickham Laboratories**  
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Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
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White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 19 Jun 2013  
**Date Tested:** 28 Jun 2013  
**Date Test Completed:** 12 Jul 2013  
**Purchase Order:** 20587

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0010883/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 19/06/2013  
**Test Article:** Clearklens Cleansinald SC Block  
**Sample Code:** -  
**Batch Ref:** FMP13165 34153  
**Qty Received:** 20 x 25mL bottles

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
Volume Tested	MM107/05	20 x 25 mL
Product Standard Data Sheet	FG047/psd	FM06

### Comments

Test carried out according to current Pharmacopoeias.

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

*Suz Wood*

Date: 16 Jul 2013 13:41:18

Mrs S.L. Wood, BSc (Hons), CBiol, MSB  
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0010883

Certificate of Analysis - OSMM

Print Number: P0011949

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