



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 02.05.13

Product Name	CLEARKLENS CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FNP 13123 34040
Production Date	05/2013
Expiration Date	05/2015

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 :	A. Matena, P. Tytushe
	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
-------------	--------------	--



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 10-Apr-2013

UK32S11012581-1-1

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:	PO20200
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.WO34036 , 2 PLTS LOT 1 THURS 4.4.13
Shop Order Number:	S11012581-1-1
Synergy Health Sales Part Reference:	1002719

## Irradiation Data

Date and Time of Irradiation:	10-Apr-2013 20:55
Reference Dose Range kGy:	33.5 - 34.6
Calculated Minimum Dose kGy:	27.7
Calculated Maximum Dose kGy:	35.4

Items Irradiated under WO34036 will be used in finished product,  
 FMP13123 34040

09.05.13. L. Cavanagh

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

contract analytical services

Wickham Laboratories Limited,  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
+44(0)1329 832511  
Fax: +44(0)1329 226688

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

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

**Date Received:** 09 May 2013  
**Date Tested:** 15 May 2013  
**Date Test Completed:** 29 May 2013  
**Purchase Order:** 20374

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0010194/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 09/05/2013  
**Test Article:** Clearklens Cleansinald SC Block  
**Sample Code:** FMP13123 34040  
**Batch Ref:** 429281  
**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.

Date: 30 May 2013 16:18:03

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

Consignment: 0010194

Certificate of Analysis - OSMM

Print Number: P0010872 Page 1 of 1