



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 28.11.13

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	7516431
Batch Number	FMP 13332 35102
Production Date	11/2013
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	9.0	11.4	10.8
Specific Gravity (20°C)	JDM004	0.990	1.010	0.994

On behalf of Diversey site Quality Manager	Name :	Amakura, L. Gaynor
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516431	Version : 04	Date of issuing : November 28 <sup>th</sup> 2011
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<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 29-Oct-2013

UK32S11066170-1-1

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

EN ISO 11137-1:2006 Sterilisation of Health Care Products  
 EN ISO 9001:2008 Quality Management System  
 EN 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

Account Number:	100432
Synergy Health Sales Part Reference:	1002720
Customer Reference Number:	P021209
Product Description:	C/SINALD SS 900ml BOTTLE 25-40kGy
Validation Reference:	4.0615
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	LOT 1, BATCH W035101, 1 PLT, THUR 24.10.13

### Irradiation Data

Date and Time of Irradiation:	29-Oct-2013 01:59
Reference Dose Range kGy:	34.8 - 35.1
Calculated Minimum Dose kGy:	28.6
Calculated Maximum Dose kGy:	36.3

Items Irradiated under W035101 will be used in finished product batch code FMP13332 35102

*E. Gwyn 29.11.13*

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 Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
Alt. Telephone: +44(0)1329 832511  
Fax: +44(0)1329 832511

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:** 02 Dec 2013  
**Date Tested:** 06 Dec 2013  
**Date Test Completed:** 20 Dec 2013  
**Purchase Order:** 21432

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0013656/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 02/12/2013  
**Test Article:** CLEARKLENS CLEANSINALD SS BLOCK  
**Sample Code:** 4934  
**Batch Ref:** FMP13332 35102  
**Qty Received:** 20 x 900mL 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	20x50 mL
Product Standard Data Sheet	FG047/psd	FM06

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 23 Dec 2013 12:42:58

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0013656

Certificate of Analysis - OSMM

Print Number: P0016354

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ISO  
17025

GLP GMP FDA

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