



Diversey Europe BV  
 Maarssebroekse dijk 2  
 3542 DN Utrecht  
 The Netherlands  
 Tel. +31 (0)30 247 6427

**CERTIFICATE OF ANALYSIS**

Date: 7.04.2017

<b>Product Name</b>	CLEARKLENS CLEANSINALD SC VH9
<b>Product Code</b>	7516429
<b>Batch Number</b>	FMP 17097 42212
<b>Production Date</b>	07/04/2017
<b>Expiration Date</b>	Exp 07/04/2019

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	12.9
Specific Gravity (20°C)	JDM004	1.040	1.060	1.048

On behalf of Diversey site Quality Manager	Name :	<i>Olga Lirenna, Pautyjes</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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Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 20 Apr 2017  
**Date Tested:** 27 Apr 2017  
**Date Test Completed:** 11 May 2017  
**Purchase Order:** 28764

**CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 0035136/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 20/04/2017  
**Test Article:** Cleansinald SC  
**Sample Code:** FMP17097 42212  
**Batch Ref:** 560747  
**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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1. USP 39 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM06

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

 CBior MKSB

Date: 12 May 2017 13:19:04

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 01-Mar-2017

UK32S11821168-1-1

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

EN ISO 11137-1:2015 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:	1002719
Customer Reference Number:	PO28453
Product Description:	C/SINALD BLK BOTT/CAPS/BAGS 25-40kGy
Validation Reference:	4.1666
Quantity Received:	33
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	11 X WO42048,11 X WO42156,11 X WO42213 MON 27 FEB 2017 6 PLTS

### Irradiation Data

Date and Time of Irradiation:	01-Mar-2017 00:55
Reference Dose Range kGy:	33.8 - 34.3
Calculated Minimum Dose kGy:	27.3
Calculated Maximum Dose kGy:	35.3

Items irradiated under WO42213 are to be used in finished product batch FMP17097 42212

*18/04/17*  
*CASAC*

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

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