



Diversey Europe BV

Maarssebroeksewijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 17.03.2015

Product Name	CLEARLENSE CLEANSINALE SC VH9
Product Code	7516429
Batch Number	FMP 15077 38223
Production Date	03 / 2015
Expiration Date	03 / 2017

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	1.050

On behalf of Diversey site Quality Manager	Name :	Opa Kirchner, Anke
	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: 05-Mar-2015

UK32S11339027-1-1

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:	1002719
Customer Reference Number:	P023887
Product Description:	C/SINALD BLK BOTT/CAPS/BAGS 25-40kGy
Validation Reference:	4.1666
Quantity Received:	11
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	B/N W037757 THUR 26 FEB 2015 2 PLTS LOT 2

## Irradiation Data

Date and Time of Irradiation:	04-Mar-2015 23:55
Reference Dose Range kGy:	33.7 - 35.2
Calculated Minimum Dose kGy:	27.2
Calculated Maximum Dose kGy:	36.2

Items irradiated under W037757 will be used in finished product batch code FMP15077 38223 *L. Gange*

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



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

**Date Received:** 20 Mar 2015  
**Date Tested:** 26 Mar 2015  
**Date Test Completed:** 17 Apr 2015  
**Purchase Order:** 24035

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0021787/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:  
PH Eur and USP  
**Date Received:** 20/03/2015  
**Test Article:** Cleansinald SC  
**Sample Code:** -  
**Batch Ref:** FMP15077 38223  
**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
Growth of Sub-culture in TSB at 20-25°C after 4 - 7 days	MM107/07	No growth in one broth
Growth of Sub-culture in THY at 30-35°C after 4 - 7 days	MM107/08	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 and position is shown below.

*Amore*

Date: 20 Apr 2015 14:12:05

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology