



Diversey Europe BV

Maarssebroekedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 5427

## CERTIFICATE OF ANALYSIS

Date: 14.12.2016

Product Name	CLEARLENSE CLEANSINALE SC VH9
Product Code	7516429
Batch Number	FMP 15320 38955
Production Date	16.11.2015
Expiration Date	16.11.2017

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	12.9
Specific Gravity (20°C)	JDM004	1.040	1.060	1.046

On behalf of Diversey site Quality Manager	Name :	Olga Kirchmaier, P. B. J. J. J.
	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: 08-Nov-2015

UK32S11492592-1-1

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:	PO25352
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 W038953 THUR 22 OCT 2015 2 PLTS LOT 3

## Irradiation Data

Date and Time of Irradiation:	08-Nov-2015 21:56
Reference Dose Range kGy:	33.7 - 34.1
Calculated Minimum Dose kGy:	27.2
Calculated Maximum Dose kGy:	35.1

Items Irradiated under W038953 will be used in finished product number : FMP15320 38955

*E. Ganev . 23.11.15*

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



# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
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:** 24 Nov 2015  
**Date Tested:** 26 Nov 2015  
**Date Test Completed:** 10 Dec 2015  
**Purchase Order:** 25532

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0025997/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest)  
**Date Received:** 24/11/2015  
**Test Article:** Cleansinald SC  
**Sample Code:** -  
**Batch Ref:** FMP15320 38955  
**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

Tested according to current Pharmacopoeias.

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

Date: 11 Dec 2015 14:27:42

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology