



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 13.8.2017

Product Name	CLEARKLENS CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FNP 17072 42048
Production Date	13.08.2017
Expiration Date	EXP 13/08/2019

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 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	1.048

On behalf of Diversey site Quality Manager	Name :	J. Stawon, H. [Signature]
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516429	Version : 03	Date of issuing : November 28 th 2011
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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 21 Mar 2017
Date Tested: 28 Mar 2017
Date Test Completed: 11 Apr 2017
Purchase Order: 28594

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0034561/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 21/03/2017
Test Article: ClearKlens Cleansinald SC
Sample Code: FMP17072 42046
Batch Ref: 560747
Qty Received: 50 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.

 CBio: MRSB

Date: 12 Apr 2017 10:51:45

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:	P028453
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 WO42048 will be used in finished product batch FMP17072 42046

Clasoe 23/03/17

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