



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 11.11.14

Product Name	CLEARLENSE CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FMP 14315 37193
Production Date	11 / 2014
Expiration Date	11 / 2016

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 :	Olga Kischner, C. Bore
	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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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 02-Nov-2014

UK32S11268602-1-1

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:	P023201
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 W037192 THUR 30.10.14 2 PLTS LOT 3

Irradiation Data

Date and Time of Irradiation:	02-Nov-2014 20:59
Reference Dose Range kGy:	33.1 - 33.5
Calculated Minimum Dose kGy:	26.7
Calculated Maximum Dose kGy:	34.4

Items irradiated under W037192 will be used in finished product batch code FMP14315 37193

L. Gwynn - 19.11.14.

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

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

Date Received: 17 Nov 2014
Date Tested: 20 Nov 2014
Date Test Completed: 04 Dec 2014
Purchase Order: 23301

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0019788/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 17/11/2014
Test Article: Cleansinald SC
Sample Code: -
Batch Ref: FMP14315 37193
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

Test carried out according to current Pharmacopoeias.

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



Date: 05 Dec 2014 18:08:45

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0019788

Certificate of Analysis - OSMM

Print Number: P0024271

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ISO
17025

GLP GMP FDA

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