



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 19.3.15

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	7516431
Batch Number	FMP 15078 37760
Production Date	03/2015
Expiration Date	09/2016

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	9.0	11.4	10.8
Specific Gravity (20°C)	JDM004	0.990	1.010	0.998

On behalf of Diversey site Quality Manager	Name :	A. Bous, Amakere
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516431	Version : 04	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 20-Feb-2015

UK32S11329862-1-1

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:	1002720
Customer Reference Number:	P023778
Product Description:	C/SINALD SS 900ml BOTTLE 25-40kGy
Validation Reference:	4.0615
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	B/N WO37759 THUR 12 FEB 2015 1 PLT LOT 2
Other Process Details:	Released against Validation 4.1909 Calculated Minimum dose 31.1 kGy, Calculated Maximum dose 38.5 kGy.

Irradiation Data

Date and Time of Irradiation:	20-Feb-2015 09:52
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Items irradiated under WO37759 will be used in finished product batch code FMP15078 37760 *E. Gwynn*

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

Contract Analytical Services

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

Date Received: 24 Mar 2015
Date Tested: 26 Mar 2015
Date Test Completed: 09 Apr 2015
Purchase Order: 24067

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0021833/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 24/03/2015
Test Article: ClearKlens Cleansinald SS
Sample Code: -
Batch Ref: FMP15078 37760
Qty Received: 20 x 900mL 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 50 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: 10 Apr 2015 15:04:44

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0021833

Certificate of Analysis - OSMM

Print Number: P0026615 Page 1 of 1

ISO
17025

GLP GMP FDA

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