



Diversey Europe BV

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The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 7.01.14

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	7516431
Batch Number	FMP14007 35489
Production Date	01 / 2014
Expiration Date	07 / 2015

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	10.9
Specific Gravity (20°C)	JDM004	0.990	1.010	0.998

On behalf of Diversey site Quality Manager	Name :	Anatara Pongkijvorakul
	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: 14-Dec-2013

UK32S11086858-1-1

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:	P021479
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:	LOT 3; 1 PLT; THUR 12.12.13; FMP B/NO. W035484

Irradiation Data

Date and Time of Irradiation:	14-Dec-2013 11:09
Reference Dose Range kGy:	33.2 - 34.5
Calculated Minimum Dose kGy:	27.3
Calculated Maximum Dose kGy:	35.7

Items Irradiated under W035484 will be used in finished product batch code, FMP14007 35489.

L. Gargan 08.01.2014

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



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

Date Received: 09 Jan 2014
Date Tested: 17 Jan 2014
Date Test Completed: 31 Jan 2014
Purchase Order: 21583

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0014214/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 09/01/2014
Test Article: CLEARKLENS CLEANSINALD SS BLOCK 1
Sample Code: 5058
Batch Ref: FMP14007 35489
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: 03 Feb 2014 10:21:47

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0014214

Certificate of Analysis - OSMM

Print Number: P0017196

Page 1 of 1

ISO
17025

GLP GMP FDA

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