



Diversey Europe Operations BV

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3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 26.10.17

Product Name	CLEARKLENS CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FHP 17299 44307
Production Date	26/10/2017
Expiration Date	Exp. 26/10/2019

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	1.052

On behalf of Diversey site Quality Manager	Name :	Opa Lina, Bartuska
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516429	Version : 04	Date of issuing : April 27 th 2012
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 18-Oct-2017

UK33S11981112-2-1

This is to certify that AST Daventry 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:	1111497
Customer Reference Number:	P029723
Product Description:	C/SINALD BOTTLES/CAPS/BAGS DV4894 25-40KGS
Validation Reference:	4894
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO43637, 2 plts

Irradiation Data

Date and Time of Irradiation:	18-Oct-2017 09:05
Reference Dose Range kGy:	30.5 - 30.8
Calculated Minimum Dose kGy:	27.8
Calculated Maximum Dose kGy:	33.8

Items irradiated under WO43637, will be used in finished product batch FMP17299 44307.

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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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Mr J Jackson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 03 Nov 2017
Date Tested: 14 Nov 2017
Date Test Completed: 05 Dec 2017
Purchase Order: PO29888

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0038939/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 03/11/2017
Test Article: Cleansinald SC
Sample Code: FMP17299 44307
Batch Ref: 578406
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
Growth of Sub-culture in TSB at 20-25°C after 4 - 7 days	MM107/07	No growth in one broth
Growth of Sub-culture in THY at 30-35°C after 4 - 7 days	MM107/08	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 40 <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.

 CB001 MKSB

Date: 06 Dec 2017 13:18:51

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology