Diversey Europe Operations BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 12.10.2017

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429		
Batch Number	FNP 17284 /44072		
Production Date	11/10/2017		
Expiration Date	EXP 11/10/2019		

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	, –	htly Yellow uid	clear slightly yellon liquid
pH (100% 20°C)	JDM001	12.0	13.0	13.0
Specific Gravity (20°C)	JDM004	1.040	1.060	1.048

On behalf of Diversey site Quality Manager	Name :	M. Stavon, Olpa Linchne.
	Position	Quality Control Inspector

This document being issued electronic	cally does not bear a signature
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COA 7516429	Version: 04	Date of issuing : April 27th 2012



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Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS Date Received:

16 Oct 2017

Date Tested:

24 Oct 2017

Date Test Completed:

15 Nov 2017

Purchase Order:

29787

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0038575/1

Test Required:

Sterility by Membrane Filtration Steritest

Date Received:

16/10/2017

Test Article:

Cleansinald SC FMP17284 44072

Sample Code: Batch Ref:

585526

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.

Muga

CBiot MKSB

Date: 17 Nov 2017 16:17:20

Mrs C Moore

Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM Consignment: 0038575 Print Number: P0047135 Page 1 of 1





http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 29-Sep-2017 UK33S11962706-2-1

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:** P029612 **Product Description:** C/SINALD BOTTLES/CAPS/BAGS DV4894 25-40KGS Validation Reference: 4894 **Ouantity Received:** 11 **Customer Minimum Specification kGy:** 25.0 **Customer Maximum Specification kGy:** 40.0 Customer Unit Lot/Batch Number: W043374, 2PLTS **Irradiation Data** Date and Time of Irradiation: 29-Sep-2017 04:59 Reference Dose Range kGy: 29.5 - 29.9 Calculated Minimum Dose kGv: 26.9 Calculated Maximum Dose kGy: 32.8

Items irradiated under WO43374, will be used in finished product batch FMP17284 44072

Irradiation Release Authorised By Synergy Health plc