Diversey Europe Operations BV

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CERTIFICATE OF ANALYSIS

Date: 15.09.15

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	100848254
Batch Number	FMP 15 258 38948
Production Date	15/09/2015
Expiration Date	15/03/2017

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
L		Lower -	Upper	
Appearance	Visual	Clear Slig	htly Yellow	Clear Slightly
		Liq	juid	Yellow Liguist
pH (100% 20°C)	JDM001	9.0	11.4	10.8
Specific Gravity (20°C)	JDM004	0.990	1.010	0.994
			-	

	0.1.1.10 CD:	Name:	4. Stava Matura	
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector		

This document being issued electronically does not bear a signature

COA 7516432 Version: 05 Date of issuing: April 27th 2012



http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 15-Oct-2015 UK32S11451300-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 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

Reference Dose Range kGy:

Calculated Minimum Dose kGy:

Calculated Maximum Dose kGy:

All in accordance with current Technical Agreement

Order information **Account Number:** 100432 Synergy Health Sales Part Reference: 1002720 **Customer Reference Number:** P024951 **Product Description:** C/SINALD SS 900ml BOTTLE 25-40kGy Validation Reference: 4.1909 **Quantity Received:** Customer Minimum Specification kGv: 25.0 **Customer Maximum Specification kGy:** 40.0 Customer Unit Lot/Batch Number: B/N W038947 THURS 20TH AUG 2015 1 PLT LOT 6 irradiation Data Date and Time of Irradiation: 02-Sep-2015 12:00

34.4 - 34.6

30.1

37.1

Items irradiated under WO38947 will be used in finished product number: FMP15258 38948

L Gareyn. 15,10.15



Wickham Laboratories Ltd Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

Telephone: Fax: +44(0)1329 226600 +44(0)1329 226688

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS Date Received:

17 Sep 2015

Date Tested:

29 Sep 2015

Date Test Completed:

13 Oct 2015

Purchase Order:

25124

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0024752/1

Test Required:

Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Date Received:

17/09/2015

Test Article:

Clearklens Cleansinald ss

Sample Code:

FMP 15258 38948

Batch Ref:

6893

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

Tested in accordance with Ph Eur 8.0 2.6.1, USP 38 <71> & JP XVI 4.06 except for volume tested.

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

Marriso

Date: 14 Oct 2015 15:41:49

Mrs C Moore

Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM Consignment: 0024752 Print Number: P0030219 Page 1 of 1

