

Diversey Europe Operations BV

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## **CERTIFICATE OF ANALYSIS**

Date: 18.05.2017

Product Name	CLEARKLENS CLEANSINALD SS VH9S		
Product Code	100848254		
Batch Number	THP17138 42640		
Production Date	18/05/2017		
Expiration Date	EXP 18/11/2018		

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
A		Lower -	Upper	
Appearance	Visual		htly Yellow Juid	Obov Slightly.
pH (100% 20°C)	JDM001	9.0	11.4	Yellow lighted
Specific Gravity (20°C)	JDM004	0.990	1.010	0.996

On behalf of Diversey site Quality Manager	Name:	T. Storm Penty Exts	
	Position	Quality Control Inspector	

This document being issued	electronically does not bear a signature	
COA 100848254	Version: 02	Date of issuing : April 7th 2016



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Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received:

25 May 2017

**Date Tested:** 

05 Jun 2017

**Date Test Completed:** 

19 Jun 2017

**Purchase Order:** 

28994

### **CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 

0035777/2

**Test Required:** 

Sterility by Membrane Filtration Steritest

Date Received:

25/05/2017

Test Article:

ClearKlens Cleansinald SS

Sample Code:

FMP17138 42640

Batch Ref:

8469

**Qty Received:** 

20 x 900mL Bottles + 1 Spare

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**

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

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

Miller

CBio, MRSB

Date: 20 Jun 2017 11:26:38

Mrs C Moore

Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM Consignment: 0035777 Print Number: P0043586

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http://www.synergyhealthpic.com

# **Certificate of Irradiation**

Date Issued: 08-May-2017

UK33S11867319-1-2

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: 1105380 **Customer Reference Number:** P028853 **Product Description:** C/SINALD SS 900ml Bottle DV4673 25-40kGy Validation Reference: 4673 **Quantity Received:** 25.0 Customer Minimum Specification kGy: **Customer Maximum Specification kGy:** 40.0 W042641, 1 PLT Customer Unit Lot/Batch Number: **Irradiation Data** Date and Time of Irradiation: 08-May-2017 03:09 Reference Dose Range kGy: 33.2 - 33.4 Calculated Minimum Dose kGy: 30.5 Calculated Maximum Dose kGy: 36.5

Items irradiated under WO42641, will be used in finished product batch FMP17138 42640

Irradiation Release Authorised By Synergy Health plc