



Diversey Europe Operations BV

Maarssenbroeksedijk 2  
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The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 25.10.17

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	100848254
Batch Number	FMP17298 - 43591
Production Date	25/10/2017
Expiration Date	EXP 25/04/2019

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	9.0	11.4	10.9
Specific Gravity (20°C)	JDM004	0.990	1.010	1.000

On behalf of Diversey site Quality Manager	Name :	Navaburda, J. Stawon
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 100848254	Version : 02	Date of issuing : April 7 <sup>th</sup> 2016
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# Wickham Laboratories

Contract Analytical Services

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

**Date Received:** 30 Oct 2017  
**Date Tested:** 02 Nov 2017  
**Date Test Completed:** 16 Nov 2017  
**Purchase Order:** 29872

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0038831/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 30/10/2017  
**Test Article:** ClearKlens Cleansinald SS  
**Sample Code:** FMP17298 43591  
**Batch Ref:** 8831  
**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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	See external comments
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.

CBIOL MKSB

Date: 17 Nov 2017 11:37:38

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 11-Oct-2017

UK33S11978978-2-1

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:	1105380
Customer Reference Number:	P029717
Product Description:	C/SINALD SS 900ml Bottle DV4673 25-40kGy
Validation Reference:	4673
Quantity Received:	11
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO43589, 2 PLTS

## Irradiation Data

Date and Time of Irradiation:	11-Oct-2017 17:37
Reference Dose Range kGy:	32.6 - 33.3
Calculated Minimum Dose kGy:	29.9
Calculated Maximum Dose kGy:	36.4

Items irradiated under WO43589, will be used in finished product batch FMP17298 43591

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