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## CERTIFICATE OF ANALYSIS

Date: 22.09.2018

Product Name	CLEARLENSE CLEANSINALD SS VH9S
Product Code	100848254
Batch Number	FMP18265 45787
Production Date	22/09/2018
Expiration Date	EXP 22/03/2020

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 (neat solution)	DM001	9.0	11.4	10.7
Specific Gravity (20°C)	DM004	0.990	1.010	0.996

On behalf of Diversey site Quality Manager	Name :	U. Karaburda E. Malik
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 <sup>th</sup> 2017
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<http://www.steris-ast.com>

# Certificate of Irradiation

Date Issued: 07-Sep-2018

UK33S12159527-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 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:	P031644
Product Description:	C/SINALD SS 900ml Bottle DV4673 25-40kGy
Validation Reference:	4673
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO45826, 1 PLT

## Irradiation Data

Date and Time of Irradiation:	07-Sep-2018 13:41
Reference Dose Range kGy:	33.2 - 33.8
Calculated Minimum Dose kGy:	30.5
Calculated Maximum Dose kGy:	36.9

Items irradiated under WO45826, will be used in finished product batch FMP18265 45787.

*C Pascoe*

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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

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:** 26 Sep 2018  
**Date Tested:** 02 Oct 2018  
**Date Test Completed:** 16 Oct 2018  
**Purchase Order:** 31805

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0044945/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 26/09/2018  
**Test Article:** ClearKlens Cleansinald SS  
**Sample Code:** FMP18265 45787  
**Batch Ref:** 9671  
**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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	See external comments
Product Standard Data Sheet	FG047/psd	FM06-01

### 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.

C. Moore MRSB

Date: 17 Oct 2018 15:30:16

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology