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## CERTIFICATE OF ANALYSIS

Date: 02.04.2019

<b>Product Name</b>	CLEARKLENS CLEANSINALD SS VH9S
<b>Product Code</b>	100848254
<b>Batch Number</b>	FMP19092 47079
<b>Production Date</b>	02.04.2019
<b>Expiration Date</b>	EXP 02/10/2020

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	Clear Slightly yellow liquid
pH (neat solution)	DM001	9.0	11.4	10.7
Specific Gravity (20°C)	DM004	0.990	1.010	0.998

On behalf of Diversey site Quality Manager	Name :	J. Slawon Navabawda
	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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Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 05 Apr 2019  
**Date Tested:** 12 Jun 2019  
**Date Test Completed:** 26 Jun 2019  
**Purchase Order:** PO32885

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0048121/3  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 05/04/2019  
**Test Article:** Clearklens Cleansinald SS  
**Sample Code:** FMP 19092 47079  
**Batch Ref:** 10106  
**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	FM06-02

### Comments

Additional sample received 28/05/19, 1 x 900mL bottle of Clearklens Cleansinald SS, Sample Code: FMP 19092 47079, Batch 10106. allocated LR 0048121/3B.

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.

 BSc CBiol MRSB

Date: 03 Jul 2019 15:03:58

Mrs P. Pham-Lengoc  
Documentation Manager – Microbiology

# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1969A

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<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD SS 900ml Bottle DV4673	WO47080, INC 1 SMPL	6	Case
Validation Reference Number: 4673			

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Processing Run Start Date: 18-Mar-19 06:32 AM

Processing Run End Date: 18-Mar-19 01:01 PM

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Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.3
Reference Dose Range (kGy):	27.3- 36.6	Calculated Max Dose (kGy):	35.3

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### Other Information

WO47080, INC 1 SMPL, 1 PLT

**Gamma Process Run Approval authorized by STERIS**

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

### Processing Location

Synergy Health Sterilisation UK  
Limited, a STERIS Company  
Brunel Close  
Drayton Fields Industrial Estate  
Daventry  
Northants  
NN11 8RB  
Phone: + 44(0) 1327 706 111

Item irradiated under WO47080 will be used in finished batch code FMP19092 47079

Olga Kirchner