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CERTIFICATE OF ANALYSIS

Date: 24/05/2019

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	100848254
Batch Number	FMP19143 47310
Production Date	23/05/2019
Expiration Date	EXP 23/11/2020

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	10.2
Specific Gravity (20°C)	DM004	0.990	1.010	0.998

On behalf of Diversey site Quality Manager	Name :	Poeygels
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of Issuing : November 24 th 2017
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-2703A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD SS 900ml Bottle DV4673	WO47311	5	Case

Validation Reference Number: 4673

PO Number: PO32901

Processing Run Start Date: 20-Apr-19 04:59 AM

Processing Run End Date: 20-Apr-19 10:45 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	30.2
Reference Dose Range (kGy):	27.3- 36.6	Calculated Max Dose (kGy):	36.1

Signature Manifest

Reviewed and E-Signed By: Mark Morse (QA Officer)

Date/Time E-Signed: 2019-04-24 03:02 PM

Document Content Revision: 2

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

Items irradiated under WO47311 will be used in finished batch FMP19143 47310

Olga Kirchner



Wickham Laboratories

Contract Analytical Services

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Hampshire PO13 0AU England
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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 02 Sep 2019
Date Tested: 12 Sep 2019
Date Test Completed: 26 Sep 2019
Purchase Order: 33232

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0049051/7
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 02/09/2019
Test Article: ClearKlens Cleansinald SS
Sample Code: FMP19143 47310
Batch Ref: 10105
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	FM06-02

Comments

3 x 900mL Bottles of Cleansinald SS, FMP19143 47310, Batch 10105 were received 05/09/2019 and allocated LR0049051/7A.

Repeat testing for LR0049051/4 due to invalid test results.

See deviation report M DEV 19/101 for details.

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: 02 Oct 2019 09:17:02

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology