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CERTIFICATE OF ANALYSIS

Date: 24|05|2019

Product Name	**CLEARKLENS CLEANSINALD SS VH9S**
Product Code	100848254
Batch Number	FHP 19143 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 :	Pouthyadi8O Uwakuda
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	*Version : 02*	*Date of issuing : November 24th 2017*

Wickham Laboratories
Contract Analytical Services

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

Date Received: 06 Jun 2019
Date Tested: 13 Sep 2019
Date Test Completed: 13 Sep 2019
Purchase Order: 33232

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0049051/4
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 06/06/2019
Test Article: Cleansinald SS
Sample Code: FMP19143 47310
Batch Ref: 10105
Qty Received: 20 x 900mL Bottles

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Invalid
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	N/A
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	N/A
Volume Tested	MM107/05	N/A
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	N/A
Product Standard Data Sheet	FG047/psd	N/A

Comments

Additional sample received 17/07/19, 1 x 900mL bottle, CleanKlens Cleansinald SS, FMP1914347310, Batch 10105. Allocated LR0049051/4A.
2 x 900mL Bottles of Cleansinald SS received 02/08/19, FP1914347310, Batch 10105. Allocated LR 0049051/4B.

See LR0049051/7 for additional testing due to this test being invalidated. See deviation report M DEV 19/101 for details.

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

BSc. CBiol. MRSB

Date: 23 Sep 2019 08:37:56

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-2703A

Product Code	Lot Number	Quantity	UOM
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