Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 07.05.2019

Product Name	**CLEARKLENS CLEANSINALD SS VH9S**
Product Code	10084825 4
Batch Number	FMP19127 47175
Production Date	07.05.2019
Expiration Date	EXP 07/11/2020

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 Lower - Upper		Results
Appearance	Visual	Clear Slightly Yellow Liquid		clear slightly yellow liquid
pH (neat solution)	DM001	9.0	11.4	9.7
Specific Gravity (20°C)	DM004	0.990	1.010	0.994

On behalf of Diversey site Quality Manager	Name :	J. Stavon Partyka sb
	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 Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Fax: +44(0)1329 226688

mail@wickhamlabs.co.uk
www.wickhamlabs.co.uk

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

Date Received: 10 May 2019
Date Tested: 07 Jun 2019
Date Test Completed: 21 Jun 2019
Purchase Order: PO33083

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0048647/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 10/05/2019
Test Article: ClearKlens Cleansinald SS
Sample Code: FMP19127 47175
Batch Ref: 10107
Qty Received: 20 x 900mL

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

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.

L. Bailey

Date: 27 Jun 2019 15:55:28

L Bailey
Laboratary Manager - Pharmaceutical Microbiology

GMP GLP FDA Audited Laboratory

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-2701A

Product Code	Lot Number	Quantity	UOM
C/SINALD SS 900ml Bottle DV4673	WO47176	6	Case

Validation Reference Number: 4673

Processing Run Start Date: 20-Apr-19 04:45 AM

Processing Run End Date: 20-Apr-19 10:30 AM

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**30.3**
Reference Dose Range (kGy):	**27.3- 36.6**	**Calculated Max Dose (kGy):**	**36.5**

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

Items irradiated under WO47176 will be used in finisched batch code Fmp19127 47175

Olga Kirchner