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CERTIFICATE OF ANALYSIS

Date: 29 05 2019

Product Name	CLEARLENSE CLEANSINALE SC VH9
Product Code	7516429
Batch Number	FMP 19149 47803
Production Date	29/05/2019
Expiration Date	Exp 29/05/2021

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	12.0	13.0	13.0
Specific Gravity (20°C)	DM004	1.040	1.060	1.050

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

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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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: 06 Jun 2019
Date Tested: 11 Jul 2019
Date Test Completed: 25 Jul 2019
Purchase Order: 33232

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0049051/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 06/06/2019
Test Article: Cleansinald SC
Sample Code: FMP19149 47803
Batch Ref: 620529
Qty Received: 20 x ~25mL Bottles + 10 Spares

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 25 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 42 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM06-02

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

 BSc. CBiol MRSB

Date: 05 Aug 2019 08:41:20

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3114A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD BOTTLES/CAPS/BAGS DV4894	WO47171	11	Case

Validation Reference Number: 4894

PO Number: PO33081

Processing Run Start Date: 17-May-19 10:18 PM

Processing Run End Date: 18-May-19 04:37 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.8
Reference Dose Range (kGy):	27.4- 36.5	Calculated Max Dose (kGy):	36.6

Other Information

WO47171, 2 PLTS

Signature Manifest

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

Date/Time E-Signed: 2019-05-20 01:36 PM

Document Content Revision: 1

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 WO47171 will be used in finished batch code Fmp19149 47803

Olga Kirchner