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: 31 Jul 2019
Date Test Completed: 14 Aug 2019
Purchase Order: 33232

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0049051/3
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 06/06/2019
Test Article: Cleansinald SC
Sample Code: FMP19148 47168
Batch Ref: 628503
Qty Received: 20 x 25mL Bottles + 15 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 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.

L. Bailey BSc

Date: 19 Aug 2019 15:20:25

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: 2173-3114A

Product Code	Lot Number	Quantity	UOM
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

Sterile Components for WO 47168 And WO 47803

Diversey Europe Opertaions BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 29-05-2019

Product Name	**CLEARKLENS CLEANSINALD SC VH9**
Product Code	7516429
Batch Number	FMP 19148 47168
Production Date	28/05/2019
Expiration Date	Exp 28/05/2021

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 Lower - Upper		Results
Appearance	Visual	Clear Slightly Yellow Liquid		Clear Slightly Yellow Liquid
pH (neat solution)	DM001	12.0	13.0	12.8
Specific Gravity (20°C)	DM004	1.040	1.060	1.050

On behalf of Diversey site Quality Manager	Name :	A. Bonys, Partyasa
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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