



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 07.06.2019

Product Name	CLEARKLENS CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FMP 19158 / 47484
Production Date	07/06/2019
Expiration Date	Exp 07/06/2021

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	12.8
Specific Gravity (20°C)	DM004	1.040	1.060	1.046

On behalf of Diversey site Quality Manager	Name :	Harabinda J. Stanon
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of issuing : November 24 <sup>th</sup> 2017
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# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-3287A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD BOTTLES/CAPS/BAGS DV4894	WO47485	11	Case

Validation Reference Number: 4894

PO Number: PO33128

Processing Run Start Date: 24-May-19 02:52 AM

Processing Run End Date: 24-May-19 10:04 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):	37.0

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 WO47485 will be used in finished batch Fmp19158 47484

Olga Kirchner



# Wickham Laboratories

Contract Analytical Services

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:** 13 Jun 2019  
**Date Tested:** 06 Aug 2019  
**Date Test Completed:** 20 Aug 2019  
**Purchase Order:** 33269

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0049164/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 13/06/2019  
**Test Article:** Cleansinald SC  
**Sample Code:** FMP19158 47484  
**Batch Ref:** 641404  
**Qty Received:** 20 x 25mL Bottles (+ 10 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.



Date: 28 Aug 2019 12:28:37

Victoria Watson  
Laboratory Manager – Microbiology