

Diversey Europe Operations BV Masrasenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 09 January 2020

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429		
Batch Number	FMP20009	48802	
Production Date	09/01/2020		
Expiration Date	EXP 09/01/2022		

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	Limi Lower	its - 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	1.056
Catonic content	DM020	14.25	15.75	14.51

On behalf of Diversey site Quality Manger	Name:	Angelika Partynska Urszula Haraburda
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24th
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-7121A

Product Code Lot N		Quantity	<u>UOM</u>				
C/SINALD BOTTLES/CAPS/BAGS DV4894	WO48801	16	Case				
Validation Reference Number: 4894							
Processing Run Start Date: 27-Dec-19 05:10 PM							
Processing Run End Date: 27-Dec-19	11:35 PM						
Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.1				
Reference Dose Range (kGy):	27.4- 36.5	Calculated Max Dose (kGy):	35.1				

PO Number: PO34486

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By: Bhavya Ramisetty (Quality Engineer)

Date/Time E-Signed: 2019-12-30 10:36 AM

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 WO48801 will be used in finished batch Fmp20009 48802.

Olga Kirchner

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Miss Caroline Pascoe

Report of Tests on: Cleansinald SC

Sample Description: Sample Code: Fmp20009 48802

06-Feb-2020

Lucideon Sample Number: UK20249-2280

Lucideon Report Number: UK20249-2280/MFEP

Date Logged: 17-Jan-2020

Date Reported:

Order Number:

Issue Number:

Date(s) of Test(s): <u>Sterility Testing</u> Membrane Filtration EP PO34594

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21-Jan-2020 to 04-Feb-2020

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

NOBOOL OB-ROD-20.

Mrs Natalie Boot Senior Business Support Assistant

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