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CERTIFICATE OF ANALYSIS

Date: 06.09.2019

Product Name	CLEARLENSE CLEANSINALE SC VH9
Product Code	7516429
Batch Number	FMP19249, 48414
Production Date	06/09/2019
Expiration Date	EXP 06/09/2021

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	12.9
Specific Gravity (20°C)	DM004	1.040	1.060	1.055

On behalf of Diversey site Quality Manager	Name :	Navalinda Pantyest
	Position	Quality Control Inspector

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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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4747A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD BOTTLES/CAPS/BAGS DV4894	WO47641	11	Case

Validation Reference Number: 4894

Processing Run Start Date: 25-Aug-19 06:58 PM

Processing Run End Date: 26-Aug-19 01:24 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 WO47641 will be used in finished batch Fmp19249 48414.

Olga Kirchner

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Cleansinald SC

Sample Description: Sample Code: FMP19249 48414

Lucideon Sample Number: (195132)-39886

Lucideon Report Number: (195132)-39886/MFEP

Issue Number: 1

Date Logged: 16-Sep-2019

Order Number: PO 33882

Date Reported: 07-Feb-2020

Date(s) of Test(s): 21-Nov-2019 to 27-Jan-2020

Sterility Testing

Membrane Filtration EP

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

Nb Boot 07-Feb-20

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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