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CERTIFICATE OF ANALYSIS

Date: 10,12.2019

Product Name	CLEARKLENS CLEANSINALD SC VH9			
Product Code	7516429			
Batch Number	FHD19344 48706			
Production Date	10/12/12019			
Expiration Date	EXP 10 12 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	Limits		Results
	Method	Lower	- Upper	
Appearance	Visual	Clear Slightly Yellow Liquid		Clear Slightly Yella
pH (neat solution)	DM001	12.0	13.0	12.8
Specific Gravity (20°C)	DM004	1.040	1.060	1.056
Cationic content	DM020	14.25	15.75	14.51

On behalf of Diversey site Quality Manager	Name:	Havaburda, T. Staron
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version: 02	Date of leaving a Marrow has pull 19942	
SOM TEMPRALE	VE131011 . UZ	Date of Issuing: November 24 2017	

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-6237A

Product CodeLot NumberQuantityUOMC/SINALD BOTTLES/CAPS/BAGSWO4870716 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 21-Nov-19 06:46 PM
Processing Run End Date: 22-Nov-19 01:04 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.7

Reference Dose Range (kGy): 27.4- 36.5 Calculated Max Dose (kGy): 36.3

PO Number: PO34291

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

Signature Manifest

Reviewed and E-Signed By: Kristen Middleton (Quality Manager)

Date/Time E-Signed: 2019-11-22 08:55 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 WO48707 will be used in finished batch Fmp19344 48706.

Olga Kirchner

Document ID: 35588

Rel Date: 08/13/2018

Last Revised in Rel 2.0.0.0

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:

Fmp19344 48706

Lucideon Sample Number: (196827)-52009

Lucideon Report Number: (196827)-52009/MFEP

Issue Number:

Date Logged:

17-Dec-2019

Order Number:

PO34778

Date Reported:

27-Jan-2020

Date(s) of Test(s):

21-Dec-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

Magaot 5-201-50

Senior Business Support Assistant