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CERTIFICATE OF ANALYSIS

Date:

13 April 2021

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429		
Batch Number	FMP21103	51944	
Production Date	13/04/2021		
Expiration Date	EXP 13/04/2023		

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	1.048
Cationic Content	DM020	14.25	15.75	14.73

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Angelika Partynska
	Position	Quality Control Inspector

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-17625A

<u>Product Code</u> <u>Lot Number</u> <u>Quantity</u> <u>UOM</u>

C/SINALD BOTTLES/CAPS/BAGS WO51559 16 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 11-Mar-21 08:31 PM
Processing Run End Date: 12-Mar-21 02:17 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 30.4

Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 37.1

PO Number: 37571

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

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 WO51559 will be used in finished batch FMP21103 51944.

Olga Kirchner

Rel Date: 08/13/2018

Document ID: 73775

Last Revised in Rel 2.0.0.0

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Cleansinald SC

Sample Description:

Sample Code: Fmp21103 51944

Lucideon Sample Number: UK211750-12227

Lucideon Report Number: UK211750-12227/MFEP

Issue Number:

Date Logged:

22-Apr-2021

Order Number:

PO 37894

Date Reported:

24-May-2021

Date(s) of Test(s):

07-May-2021 to 21-May-2021

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

Mrs Andrea Saunders

Business Support Administrator