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CERTIFICATE OF ANALYSIS

Date:

11 January 2022

Product Name	CLEARKLENS CLEANSINALD SC VH9 7516429		
Product Code			
Batch Number	FMP22011	53398	
Production Date	11/01/2022		
Expiration Date	EXP 11/01/2024		

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	1.047
Cationic Content	DM020	14.25	15.75	15.46

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda 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 2173-24845A

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

C/SINALD BOTTLES/CAPS/BAGS 53435 15 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 11-Dec-2021 9:56 PM

Processing Run End Date: 12-Dec-2021 3:38 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 27.7

Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 34.1

PO Number: 401473

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 12-Dec-2021 6:09 AM

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 WO53435 will be used to finished batch FMP22011 53398.

Olga Kirchner

Document ID: 97685

N/A Last Revised in Rel 2.0.0.0 Rel Date: 13-Aug-2018 Page 1 of 1

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: FMP22011 53398

Lucideon Sample Number: UK22415-2733

Lucideon Report Number: UK22415-2733/MFEP

Issue Number:

Date Logged:

28-Jan-2022

Order Number:

PO401809

Date Reported:

17-Feb-2022

Date(s) of Test(s):

01-Feb-2022 to 15-Feb-2022

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

nr 17-feb-22

Mrs Natalie Boot

Senior Business Support Administrator

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Stoke-on-Trent