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CERTIFICATE OF ANALYSIS

Date: 08/04/2020

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429		
Batch Number	FMP 20099 119216		
Production Date	08/04/2020		
Expiration Date	Exp 08/04/2022		

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	Limits		Results	
	Method	Lower -	Upper		
Appearance	Visual	Clear Slightly Yellow Liquid		Clear Slighty Tello	
pH (neat solution)	DM001	12.0	13.0	12.9	
Specific Gravity (20°C)	DM004	1.040	1.060	1.048	
Cationic content	DM020	14.25	15.75	14.51	

On behalf of Diversey site Quality Manager	Name:	A. Booms T. Staron
	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: 2173-9053A

Product CodeLot NumberQuantityUOMC/SINALD BOTTLES/CAPS/BAGSWO4921716 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 18-Mar-20 05:21 PM
Processing Run End Date: 18-Mar-20 11:14 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.0

Reference Dose Range (kGy): 27.4-36.5 Calculated Max Dose (kGy): 37.6

PO Number: 34935

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 WO49217 will be used in finished batch Fmp 20099 49216.

Olga Kirchner

Document ID: 46005

Last Revised in Rel 2.0.0.0

Rel Date: 08/13/2018 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: Fmp 20099 49216

Lucideon Sample Number: UK201788-13599

Lucideon Report Number: UK201788-13599/MFEP

Issue Number:

Date Logged:

22-Apr-2020

Order Number:

PO 35276

Date Reported:

02-Jun-2020

Date(s) of Test(s):

14-May-2020 to 01-Jun-2020

Sterility Testing Membrane Filtration EP

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

End of Test Report



Mrs Natalie Boot

Senior Business Support Assistant