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CERTIFICATE OF ANALYSIS

Date:

08 April 2021

Product Name	CLEARKLENS CLEANSINALD SS VH9S		
Product Code	100848254		
Batch Number	FMP21098	51398	
Production Date	08/04/2021		
Expiration Date	EXP 08/10/2022		

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 Method	Test Method Limits		Results	
		Lower	- Upper		
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid	
pH (neat solution)	DM001	9.0	11.4	10.5	
Specific Gravity (20°C)	DM004	0.990	1.010	0.997	

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
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-16373A

C/SINALD SS 900ml Bottle DV4673 WO51323 13 Case

Validation Reference Number: 4673

Processing Run Start Date: 20-Jan-21 02:23 PM

Processing Run End Date: 20-Jan-21 07:48 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.1

Reference Dose Range (kGy): 27.3 - 36.6 Calculated Max Dose (kGy): 36.4

PO Number: 37188

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 WO51323 will be used in finished batch FMP21098 51398.

Olga Kirchner

Rel Date: 08/13/2018

Document ID: 69771

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 SS

Sample Description:

Sample Code: FMP21098 51398

Lucideon Sample Number: UK211643-11481

Lucideon Report Number: UK211643-11481/MFEP

Issue Number:

Date Logged:

15-Apr-2021

Order Number:

PO 37844

Date Reported:

20-May-2021

Date(s) of Test(s):

05-May-2021 to 19-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

Business Support Administrator

Mrs Andrea Saunders

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