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CERTIFICATE OF ANALYSIS

Date 10 March 2023

Product Name	CLEAI	CLEARKLENS CLEANSINALD SS VH9S		
Product Code	100848254			
Batch Number	FMP23069	56390		
Production Date	10/03/2023			
Expiration Date	EXP 10/09/2024			

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	9.0	11.4	10.8
Specific Gravity (20°C)	DM004	0.990	1.010	0.997

On behalf of Diversey site Quality Manger	Name:	Angelíka Partynska Edyta Rodrígues
	Position	Quality Control Inspector

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COA Template	Version : 04	Date of issuing : March 11th 2019
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STERIS: Gamma Certificate Of Processing

Prepared for:

FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID

2173-34943A

Product Code

Lot Number

Quantity

UOM

C/SINALD SS 900ml Bottle DV4673

56444

13 Case

Validation Reference Number:

4673

Processing Run Start Date: 11-Feb-2023 5:19 PM

Processing Run End Date: 11-Feb-2023 10:58 PM

25.0 - 40.0

Calculated Min Dose (kGy):

28.6

Reference Dose Range (kGy):

Specified Dose Range (kGy):

27.3 - 36.6

Calculated Max Dose (kGy):

Rel Date: 13-Aug-2018

34.6

PO Number: 404534

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 12-Feb-2023 8:12 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 WO56444 will be used in finished batch Fmp23069 56390.

Olga Kirchner

Document ID: 13540

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 SS

Sample Description:

Sample Code: Fmp23069 56390

Lucideon Sample Number: UK23950-6394

Lucideon Report Number: UK23950-6394/MFEP

Issue Number:

1

Date Logged:

15-Mar-2023

Order Number:

404818

Date Reported:

04-Apr-2023

Date(s) of Test(s):

20-Mar-2023 to 03-Apr-2023

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

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Mrs Natalie Boot

Senior Business Support Administrator