

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 19 January 2023

Product Name	CLEAR	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429			
Batch Number	FMP23018	55456		
Production Date	18/01/2023			
Expiration Date	EXP 18/01/2025			

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	13.0
Specific Gravity (20°C)	DM004	1.040	1.060	1.051
Cationic Content	DM020	14.25	15.75	15.25

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda Angelika Partynska
	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

2173-33824A

Product Code

Lot Number

Quantity **UOM**

C/SINALD BOTTLES/CAPS/BAGS

55546

15

DV4894

Validation Reference Number:

Case

Processing Run Start Date: 22-Dec-2022 11:24 PM

Processing Run End Date: 23-Dec-2022 4:55 AM

Specified Dose Range (kGy):

25.0 - 40.0

Calculated Min Dose (kGy):

26.9

Reference Dose Range (kGy):

27.4 - 36.5

Calculated Max Dose (kGy):

33.3

PO Number: 404209

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 23-Dec-2022 6:57 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 WO55546 will be used in finished batch Fmp23018 55456.

Olga Kirchner

Document ID: 131556

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: Fmp23018 55456

Lucideon Sample Number: UK23245-1805

Lucideon Report Number: UK23245-1805/MFEP

Issue Number:

Date Logged:

23-Jan-2023

Order Number:

404371

Date Reported:

13-Feb-2023

Date(s) of Test(s):

27-Jan-2023 to 10-Feb-2023

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

10+ Bleb23

Mrs Natalie Boot

Senior Business Support Administrator

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested.