

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date: 26/07/2021

Product Name	CLEARKLENS CLEANSINALD SC VH9	
<b>Product Code</b>	7516429	
Batch Number	FMP21207 52084	
Production Date	26/07/2021	
<b>Expiration Date</b>	EXP 26/07/2023	

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		ntly Yellow uid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	12.0	13.0	12.8
Specific Gravity (20°C)	DM004	1.040	1.060	1,044
Cationic content	DM020	14.25	15.75	15.65

On behalf of Diversey site  Quality Manager	Name:	и.Haraburda J.Staron
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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	COA Template	Version: 04	Date of issuing: March 11th 2019	

# **STERIS: Gamma Certificate Of Processing**

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-21031A

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

C/SINALD BOTTLES/CAPS/BAGS WO52085 16 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 17-Jul-2021 9:29 AM Processing Run End Date: 17-Jul-2021 3:26 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.4

Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 36.1

PO Number: 400253

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 WO52085 will be used in finished batch FMP21207 52084.

Olga Kirchner

Document ID: 84587

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Last Revised in Rel 2.0.0.0 Rel Date: 13-Aug-2018

# 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: FMP21207 52084

Lucideon Sample Number: UK213345-22615

Lucideon Report Number: UK213345-22615/MFEP

Issue Number:

Date Logged:

05-Aug-2021

Order Number:

400525

12-Aug-2021 to 31-Aug-2021

**Date Reported:** 

31-Aug-2021

Date(s) of Test(s):

**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** 

NOBOOF 31-R9-21

Mrs Natalie Boot

**Business Support Administrator**