

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 14/01/2021

Product Name	CLEARKLENS CLEANSINALD SC VH9 7516429		
Product Code			
Batch Number	FMP21014 51128		
<b>Production Date</b>	14/01/2021		
<b>Expiration Date</b>	EXP 14/01/2023		

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 Method	Lin Lower	nits - Upper	Results	
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	1,048	
Cationic content	DM020	14.25	15.75	14.73	

On behalf of Diversey site  Quality Manager	Name:	Partyer 86, Navalundo
	Position	Quality Control Inspector

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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: 2173-15900A

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

C/SINALD BOTTLES/CAPS/BAGS WO51127 16 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 18-Dec-20 07:03 PM
Processing Run End Date: 19-Dec-20 01:10 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 28.6

Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 35.5

PO Number: 37043

### 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 Iraadiated under WO51127 will be used in finished batch Fmp21014 51128.

Olga Kirchner

Document ID: 67736

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 LA1 4XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Cleansinald SC

Sample Description:

Sample Code: Fmp21014 51128

Lucideon Sample Number: UK21310-2064

Lucideon Report Number: UK21310-2064/MFEP

Issue Number:

Date Logged:

22-Jan-2021

Order Number:

PO 37271

**Date Reported:** 

19-Feb-2021

Date(s) of Test(s):

04-Feb-2021 to 18-Feb-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** 

CBOOK 19-Feb-21

Mrs Natalie Boot

**Business Support Administrator**