

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427 www.Diversey.com

#### **CERTIFICATE OF ANALYSIS**

Date: 06 February 2023

Product Name	CLEAF	CLEARKLENS CLEANSINALD SC VH9			
Product Code	7516429				
Batch Number	FMP23034	55811			
<b>Production Date</b>	03/02/2023				
<b>Expiration Date</b>	EXP 03/02/2025				

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	12.75
Specific Gravity (20°C)	DM004	1.040	1.060	1.043
Cationic Content	DM020	14.25	15.75	15.48

On behalf of Diversey site Quality Manger	Name:	Edyta Rodrígues Justyna Staron
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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

2173-34522A

**Product Code** 

Lot Number

Quantity

UOM

C/SINALD BOTTLES/CAPS/BAGS

55878

15 Case

DV4894

Validation Reference Number:

4894

Processing Run Start Date: 27-Jan-2023 9:42 AM

Processing Run End Date: 27-Jan-2023 3:24 PM

Specified Dose Range (kGy):

25.0 - 40.0

Calculated Min Dose (kGy):

27.7

Reference Dose Range (kGy):

27.4 - 36.5

Calculated Max Dose (kGy):

34.4

PO Number: 404384

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

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 27-Jan-2023 6:20 PM

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 WO55878 will be used in finished batch Fmp23034 55811.

Olga Kirchner

Document ID: 134009

## 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: Fmp23034 55811

Lucideon Sample Number: UK23481-3295

Lucideon Report Number: UK23481-3295/MFEP

Issue Number:

Date Logged:

09-Feb-2023

Order Number:

404538

Date Reported:

06-Mar-2023

Date(s) of Test(s):

15-Feb-2023 to 05-Mar-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** 



Mrs Natalie Boot

Senior Business Support Administrator