

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

## **CERTIFICATE OF ANALYSIS**

Date:

27 January 2021

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429		
Batch Number	FMP21027	51467	
Production Date	27/01/2021		
Expiration Date	EXP 27/01/2023		

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

est Test Method		Lim	its	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	1.052

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Angelika Partynska
	Position	Quality Control Inspector

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COA Template Version: 02 Date of issuing: November 24th

# **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 irradiated under WO51127 will be used in finished batch Fmp21027 51467.

Olga Kirchner

Rel Date: 08/13/2018

Document ID: 67736

Last Revised in Rel 2.0.0.0

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

Mrs.Olga Kirchner FAO:

Report of Tests on:

Cleansinald SC

Sample Description:

Sample Code: Fmp21027 51467

Lucideon Sample Number: UK21397-2622

Lucideon Report Number: UK21397-2622/MFEP

Issue Number:

1

Date Logged:

29-Jan-2021

Order Number:

PO 37328

**Date Reported:** 

25-Feb-2021

Date(s) of Test(s):

06-Feb-2021 to 24-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** 



Mrs Natalie Boot

**Business Support Administrator**