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## CERTIFICATE OF ANALYSIS

Date: 02.10.2019

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	100848254
Batch Number	FMP 19275 / 48547
Production Date	02.10.2019
Expiration Date	EXP 02/04/2021

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	clear slightly yellow liquid
pH (neat solution)	DM001	9.0	11.4	10.6
Specific Gravity (20°C)	DM004	0.990	1.010	0.995

On behalf of Diversey site Quality Manager	Name :	J. Staan, A. Bony
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of Issuing : November 24 <sup>th</sup> 2017
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# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4851A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD SS 900ml Bottle DV4673	WO48045	11	Case
Validation Reference Number: 4673			

Processing Run Start Date: 26-Aug-19 07:11 AM

Processing Run End Date: 26-Aug-19 01:32 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.7
Reference Dose Range (kGy):	27.3- 36.6	Calculated Max Dose (kGy):	35.6

**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 WO48045 will be used in finished product Fmp19275 48547.

Olga Kirchner

# PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Mrs.Olga Kirchner

**Report of Tests on:** Cleansinald SS

**Sample Description:** Sample Code: FMP19275 48547

**Lucideon Sample Number:** (195535)-42393

**Lucideon Report Number:** (195535)-42393/MFEP

**Issue Number:** 1

**Date Logged:** 07-Oct-2019

**Order Number:** 34035

**Date Reported:** 08-Nov-2019

**Date(s) of Test(s):** 25-Oct-2019 to 08-Nov-2019

### 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**

*Natalie Boot 08-Nov-19*

Mrs Natalie Boot

**Senior Business Support Assistant**

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