



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 10.09.2019

Product Name	CLEARKLENS CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FMP 19253, 47642
Production Date	10.09.2019
Expiration Date	EXP 10/09/2021

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 Liquid	clear slightly yellow liquid
pH (neat solution)	DM001	12.0	13.0	13
Specific Gravity (20°C)	DM004	1.040	1.060	1.055

On behalf of Diversey site Quality Manager	Name :	J. Staveren, 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: 2173-4746A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD BOTTLES/CAPS/BAGS DV4894	WO47643	11	Case

Validation Reference Number: 4894

Processing Run Start Date: 25-Aug-19 06:46 PM

Processing Run End Date: 26-Aug-19 01:08 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.9
Reference Dose Range (kGy):	27.4- 36.5	Calculated Max Dose (kGy):	36.4

**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 WO47643 will be used in finished batch FMP19253 47642

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 SC

**Sample Description:** Sample Code: FMP19253 47642

**Lucideon Sample Number:** (195132)-39887

**Lucideon Report Number:** (195132)-39887/MFEP

**Issue Number:** 1

**Date Logged:** 16-Sep-2019

**Order Number:** PO 33882

**Date Reported:** 03-Jan-2020

**Date(s) of Test(s):** 21-Nov-2019 to 03-Jan-2020

### 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 03-Jan-20

Mrs Natalie Boot

**Senior Business Support Assistant**

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Lucideon Limited  
Queens Road, Penkhull  
Stoke-on-Trent  
Staffordshire ST4 7LQ

T +44 (0)1782 764428  
enquiries@lucideon.com  
www.lucideon.com