



Diversey Europe BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 26.01.2021

<b>Product Name</b>	<b>CLEARLEN S CLEANSINALD SS VH9S</b>
<b>Product Code</b>	<b>7516431</b>
<b>Batch Number</b>	<b>FMP21026 51468</b>
<b>Production Date</b>	<b>26.01.2021</b>
<b>Expiration Date</b>	<b>EXP 26/07/2022</b>

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
pH (neat solution)	DM001	9.0	11.4	10.6
Specific Gravity (20°C)	DM004	0.990	1.010	0.997

On behalf of Diversey site Quality Manager	Name :	J.Staron A.Partynska
	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: 2173-15901A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD SS 900ml Bottle DV4673	WO51129	11	Case
Validation Reference Number: 4673			

Processing Run Start Date: 19-Dec-20 02:00 AM

Processing Run End Date: 19-Dec-20 07:29 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.9
Reference Dose Range (kGy):	27.3 - 36.6	Calculated Max Dose (kGy):	36.6

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 WO51129 will be used in finished batch Fmp21026 51468.

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: Fmp21026 51468

**Lucideon Sample Number:** UK21397-2621

**Lucideon Report Number:** UK21397-2621/MFEP

**Issue Number:** 1

**Date Logged:** 29-Jan-2021

**Order Number:** PO 37328

**Date Reported:** 22-Feb-2021

**Date(s) of Test(s):** 06-Feb-2021 to 20-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**

NcBoot 22-feb-21

Mrs Natalie Boot

**Business Support Administrator**

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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