



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 05/06/2020

Product Name	CLEARLENSE CLEANSINALE SS VH9S
Product Code	100848254
Batch Number	FMP20157, 49702
Production Date	05/06/2020
Expiration Date	EXP 05/12/2021

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	9.0	11.4	10.4
Specific Gravity (20°C)	DM004	0.990	1.010	0.997

On behalf of Diversey site Quality Manager	Name :	Navabunda Parthasarathy
	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
--------------	--------------	--

# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-10440A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD SS 900ml Bottle DV4673	WO49701	11	Case

Validation Reference Number: 4673

Processing Run Start Date: 11-May-20 08:05 AM

Processing Run End Date: 11-May-20 01:32 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.1
Reference Dose Range (kGy):	27.3- 36.6	Calculated Max Dose (kGy):	34.4

PO Number: PO35405

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 WO49701 will be used in finished batch Fmp20157 49702.

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: Fmp20157 49702

**Lucideon Sample Number:** UK202433-17841

**Lucideon Report Number:** UK202433-17841/MFEP **Issue Number:** 1

**Date Logged:** 12-Jun-2020 **Order Number:** PO 36575

**Date Reported:** 06-Jul-2020 **Date(s) of Test(s):** 21-Jun-2020 to 05-Jul-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**



06 JUL 20

Mrs Andrea Saunders

**Business Support Assistant**

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.

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

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