



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 10.10.2019

Product Name	CLEARLENSS CLEANSINALD SS VH9S
Product Code	100848254
Batch Number	FMP19283, 48101
Production Date	10/10/2019
Expiration Date	EXP 10/04/2021

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 Liquid	clear slightly yellow liquid
pH (neat solution)	DM001	9.0	11.4	10.8
Specific Gravity (20°C)	DM004	0.990	1.010	0.995

On behalf of Diversey site Quality Manager	Name :	Monaburda Rautjes
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of Issuing : November 24 th 2017
--------------	--------------	--

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-5396A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD SS 900ml Bottle DV4673	WO48102	11	Case

Validation Reference Number: 4673

Processing Run Start Date: 28-Sep-19 06:16 AM

Processing Run End Date: 28-Sep-19 12:34 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.7
Reference Dose Range (kGy):	27.3- 36.6	Calculated Max Dose (kGy):	36.1

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 WO48102 used in finished batch Fmp19283 48101

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: Fmp19283 48101

Lucideon Sample Number: (195849)-44544

Lucideon Report Number: (195849)-44544/MFEP

Issue Number: 1

Date Logged: 23-Oct-2019

Order Number: 34113

Date Reported: 15-Nov-2019

Date(s) of Test(s): 31-Oct-2019 to 14-Nov-2019

Sterility Testing

Membrane Filtration EP

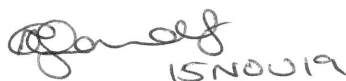
Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report



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