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CERTIFICATE OF ANALYSIS

Date: 02.02.2021

Product Name	CLEARLEN S CLEAN SINALD SS VH9S
Product Code	100848254
Batch Number	FMP21033 51137
Production Date	02.02.2021
Expiration Date	EXP 02/08/2022

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 Liquid	Yellow	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	9.0	11.4	10.8
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 th 2017
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-15902A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C/SINALD SS 900ml Bottle DV4673	WO51136	13	Case
Validation Reference Number: 4673			

Processing Run Start Date: 24-Dec-20 12:34 AM

Processing Run End Date: 24-Dec-20 05:58 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.9
Reference Dose Range (kGy):	27.3 - 36.6	Calculated Max Dose (kGy):	36.0

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 WO51136 will be used in finished batch Fmp 21033 51137.

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: Fmp21033 51137

Lucideon Sample Number: UK21568-3974

Lucideon Report Number: UK21568-3974/MFEP

Issue Number: 1

Date Logged: 09-Feb-2021

Order Number: PO 37402

Date Reported: 26-Feb-2021

Date(s) of Test(s): 11-Feb-2021 to 25-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

Natalie Boot 26-Feb-21

Mrs Natalie Boot

Business Support Administrator

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