

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 26 April 2023

Product Name	CLEARKLENS CLEANSINALD SS VH9S				
Product Code	100848254				
Batch Number	FMP23116 56827				
Production Date	26/04/2023				
Expiration Date	EXP 26/10/2024				

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	9.1
Specific Gravity (20°C)	DM004	0.990	1.010	0.996

On behalf of Diversey site	Name:	Justyna Staron	Natlía Traíchel
Quality Manger	Position	Quality (Control Inspector

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COA Template Version: 04 Date of issuing: March 11th	2019	
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-36187A

Product Code Lot Number Quantity UOM

C/SINALD SS 900ml Bottle DV4673 56860 13 Case

Validation Reference Number: 4673

Processing Run Start Date: 31-Mar-2023 4:16 PM

Processing Run End Date: 31-Mar-2023 10:12 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.8

Reference Dose Range (kGy): 27.3 - 36.6 Calculated Max Dose (kGy): 37.3

PO Number: 404909

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 01-Apr-2023 5:56 AM

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 WO56860 will be used in finished batch Fmp23116 56827.

Olga Kirchner

Document ID: 139568

N/A Last Revised in Rel 2.0.0.0 Rel Date: 13-Aug-2018 Page 1 of 1

PHARMACEUTICAL ANALYSIS REPORT



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: Fmp23116 56827

Lucideon Sample Number: UK231566-10984

Lucideon Report Number: UK231566-10984/MFEP Issue Number: 1

Date Logged: 28-Apr-2023 Order Number: 405150

Date Reported: 18-May-2023 **Date(s) of Test(s):** 03-May-2023 **to** 17-May-2023

Sterility Testing
Membrane Filtration EP

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

End of Test Report

-DocuSigned by:

Natalie Boot

Signer Name: Natalie Boot

Signing Reason: I have reviewed this document Signing Time: 18 May 2023 | 14:07 BST 90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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