

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 02.02.2021

Product Name	CLEARKLENS CLEANSINALD SS VH9S		
Product Code	100848254		
Batch Number	FMP21033 51549		
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 Lower -	Limits		Results Clear Slightly Yellow Liquid
		Upper		
Appearance	Visual	Clear Slightly Yellow Liquid		
pH (neat solution)	DM001	9.0	11.4	10.6
Specific Gravity (20°C)	DM004	0.990	1.010	0.997

	Name:	J.Staron A.Partynska
On behalf of Diversey site		
Quality Manager	Position	Quality Control Inspector

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COA Template	Version: 02	Date of issuing: November 24th 2017
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-15903A

<u>Product Code</u> <u>Lot Number</u> <u>Quantity</u> <u>UOM</u>

C/SINALD SS 900ml Bottle DV4673 WO51131 13 Case

Validation Reference Number: 4673

Processing Run Start Date: 24-Dec-20 12:18 AM

Processing Run End Date: 24-Dec-20 05:43 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.2

Reference Dose Range (kGy): 27.3 - 36.6 Calculated Max Dose (kGy): 35.7

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 WO51131 will be used in finished batch Fmp21033 51549.

Olga Kirchner

Document ID: 68164

Last Revised in Rel 2.0.0.0

Rel Date: 08/13/2018 Page 1 of 1

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Cleansinald SS

Sample Description:

Sample Code: Fmp21033 51549

Lucideon Sample Number: UK21568-3976

Lucideon Report Number: UK21568-3976/MFEP

Issue Number:

Date Logged:

09-Feb-2021

Order Number:

PO 37402

Date Reported:

01-Mar-2021

Date(s) of Test(s):

12-Feb-2021 to 26-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

15-70M-10 1 Mrs Natalie Boot

Business Support Administrator