

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 14/11/2020

Product Name	CLEARKLENS CLEANSINALD SS VH9S		
Product Code	100848 254		
Batch Number	FHP 20318 50730		
Production Date	13/11/2020		
<b>Expiration Date</b>	EXP13/05/ 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	Lin Lower	nits · Upper	Results	
Appearance	Visual	Clear Slightly Yellow Liquid		Clear Stightly	
pH (neat solution)	DM001	9.0	11.4	10.0	
Specific Gravity (20°C)	DM004	0.990	1.010	0.997	

On behalf of Diversey site Quality Manager	Name:	A. Partyindo, E. Mals
	Position	Quality Control Inspector

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COA Template	Version: 02	Date of Issuing: November 24 2017
	VEIDION I GE	Date of Bound . November 24 2017

## **STERIS: Gamma Certificate Of Processing**

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-14376A

Product Code Lot Number Quantity UOM

C/SINALD SS 900ml Bottle DV4673 WO50729 13 Case

Validation Reference Number: 4673

Processing Run Start Date: 16-Oct-20 09:55 AM

Processing Run End Date: 16-Oct-20 07:45 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 28.6

Reference Dose Range (kGy): 27.3 - 36.6 Calculated Max Dose (kGy): 36.0

PO Number: 36617

### 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 WO50729 will be used in finished batch Fmp20318 50730.

Olga Kirchner

Document ID: 62610

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: Fmp20318 50730

Lucideon Sample Number: UK204707-33230

Lucideon Report Number: UK204707-33230/MFEP

Issue Number:

Date Logged:

18-Nov-2020

Order Number:

PO 36848

Date Reported:

11-Dec-2020

Date(s) of Test(s):

27-Nov-2020 to 11-Dec-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** 

Mrs Andrea Saunders

**Business Support Assistant** 

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Lucideon Limited

Stoke-on-Trent