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## **CERTIFICATE OF ANALYSIS**

Date: 13/08/2020

Product Name	CLEARKLENS CLEANSINALD SS VH9S			
Product Code	7516431			
Batch Number	FHP 20225 50197			
Production Date	12 08 2020			
<b>Expiration Date</b>	Exp 12  02   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  Visual	Limits		Results
		Lower -	Upper	
Appearance		Clear Slightly Yellow Liquid		Yellow Liquid
pH (neat solution)	DM001	9.0	11.4	10.6
Specific Gravity (20°C)	DM004	0.990	1.010	0,997

On behalf of Diversey site	Name:	A. Borys, Islaun	
Quality Manager	Position	Quality Control Inspector	

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

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

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-12099A

Product CodeLot NumberQuantityUOMC/SINALD SS 900ml Bottle DV4673WO5018811 Case

Validation Reference Number: 4673

Processing Run Start Date: 22-Jul-20 04:50 PM

Processing Run End Date: 22-Jul-20 10:26 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.0

Reference Dose Range (kGy): 27.3-36.6 Calculated Max Dose (kGy): 35.6

PO Number: 35939

### 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 WO50188 will be used in finished batch FMP20225 50197.

Olga Kirchner

Document ID: 55760

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: Fmp20225 50197

Lucideon Sample Number: UK203475-24443

Lucideon Report Number: UK203475-24443/MFEP

Issue Number:

1

Date Logged:

26-Aug-2020

**Order Number:** 

PO 36272

**Date Reported:** 

21-Sep-2020

Date(s) of Test(s):

04-Sep-2020 to 18-Sep-2020

**Sterility Testing** 

Membrane Filtration EP

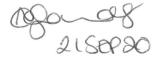
**Test Results:** 

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**