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# **CERTIFICATE OF ANALYSIS**

Date:

27 May 2020

Product Name	CLEARKLENS CLEANSINALD SC VH9 7516429		
Product Code			
Batch Number	FMP20148	50187	
Production Date	27/05/2020		
Expiration Date	EXP 27/05/2022		

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	Limits		Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	12.0	13.0	12.9
Specific Gravity (20°C)	DM004	1.040	1.060	1.048
Cationic Content	DM020	14.25	15.75	14.51

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Angelika Partynska
	Position	Quality Control Inspector

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COA Template Version: 02 Date of issuing: November 24th

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

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-10442A

Product CodeLot NumberQuantityUOMC/SINALD BOTTLES/CAPS/BAGSWO4960416 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 11-May-20 12:48 AM Processing Run End Date: 11-May-20 07:00 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.3 Reference Dose Range (kGy): 27.4- 36.5 Calculated Max Dose (kGy): 36.8

PO Number: PO35405

## 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 WO49604 will be used in finished batch Fmp20148 50187.

Olga Kirchner

Document ID: 50265

Last Revised in Rel 2.0.0.0

Rel Date: 08/13/2018

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO: Mrs.Olga Kirchner

Report of Tests on:

Cleansinald SC

Sample Description:

Sample Code: Fmp20148 50187

Lucideon Sample Number: UK202327-16968

Lucideon Report Number: UK202327-16968/MFEP

Issue Number:

1

Date Logged:

05-Jun-2020

Order Number:

PO35608

Date Reported:

26-Jun-2020

Date(s) of Test(s):

08-Jun-2020 to 26-Jun-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** 

NOBOCK 26-JUN-20

Mrs Natalie Boot

Senior Business Support Assistant