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## **CERTIFICATE OF ANALYSIS**

Date: 26/07/2021

Product Name	CLEARKLENS CLEANSINALD SC VH9 7516429		
Product Code			
Batch Number	FMP21211 52722		
Production Date	30/07/2021		
Expiration Date	EXP 30/07/2023		

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 Lower - Upper Clear Slightly Yellow Liquid		Results
ppearance				Clear Slightly Yellow Liquid
pH (neat solution)	DM001	12.0	13.0	12.8
Specific Gravity (20°C)	DM004	1.040	1.060	1.048
Contionic content	DM020	14.25	15.75	15.03

On habits CD'	Name:	U.Haraburda, J.Staron
On behalf of Diversey site  Quality Manager	Position	Quality Control Inspector

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COA Template	Version: 04	Date of issuing: March 11th 2019

## STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-21031A

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

C/SINALD BOTTLES/CAPS/BAGS WO52085 16 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 17-Jul-2021 9:29 AM Processing Run End Date: 17-Jul-2021 3:26 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.4

Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 36.1

PO Number: 400253

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

### 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 WO52085 will be used in finished batch FMP21211 52722.

Olga Kirchner

Rel Date: 13-Aug-2018

Document ID: 84587

Last Revised in Rel 2.0.0.0

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# 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: FMP21211 52722

Lucideon Sample Number: UK213345-22616

Lucideon Report Number: UK213345-22616/MFEP

Issue Number:

Date Logged:

05-Aug-2021

Order Number:

400525

Date Reported:

27-Aug-2021

Date(s) of Test(s):

12-Aug-2021 to 26-Aug-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** 

