

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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# **CERTIFICATE OF ANALYSIS**

Date: 30.11.2010

Product Name	CLEARKLENS CLEANSINALD SC VH9				
Product Code	7516429				
Batch Number	FMP20355, 51195				
Production Date	30.11.2020				
Expiration Date	EXP 30[11[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	st Test Limits		mits	Results
	Method	Lower	- Upper	
Appearance	Visual		ntly Yellow uid	clear slightly
pH (neat solution)	DM001	12.0	13.0	12.0
Specific Gravity (20°C)	DM004	1.040	1.060	048
Cationic content	DM020	14.25	15.75	15.52

On behalf of Diversey site  Quality Manager	Name :	Garay, Partywyt
	Position	Quality Control Inspector

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

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

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-14563A

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

C/SINALD BOTTLES/CAPS/BAGS WO50731 16 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 31-Oct-20 07:33 AM

Processing Run End Date: 31-Oct-20 01:22 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 28.5 Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 35.1

PO Number: 36654

### 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 WO50731 will be used in finished batch Fmp20335 51195.

Olga Kirchner

Rel Date: 08/13/2018

Document ID: 63779

Last Revised in Rel 2.0.0.0

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

Mrs.Olga Kirchner

Report of Tests on:

Cleansinald SC

Sample Description:

Sample Code: Fmp20335 51195

Lucideon Sample Number: UK204945-34350

Lucideon Report Number: UK204945-34350/MFEP

Issue Number:

Date Logged:

03-Dec-2020

Order Number:

PO 36957

Date Reported:

18-Feb-2021

Date(s) of Test(s):

28-Jan-2021 to 16-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** 

BOOK 18-Feb-21

Mrs Natalie Boot

of the results or their implications.

**Business Support Administrator**