

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### **CERTIFICATE OF ANALYSIS**

Date:

04 November 2022

Product Name	CLEARKLENS CLEANSINALD SC VH9			
Product Code	7516429			
Batch Number	FMP22307	55253		
Production Date	03/11/2022			
Expiration Date	EXP 03/11/2024			

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	12.8
Specific Gravity (20°C)	DM004	1.040	1.060	1.048
Cationic Content	DM020	14.25	15.75	15.64

On behalf of Diversey site  Quality Manger	Name:	urszula Haraburda Angelika Partynska
	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

2173-31891A

**Product Code** 

Lot Number

Quantity

C/SINALD BOTTLES/CAPS/BAGS

DV4894

55277

Case

UOM

Validation Reference Number:

Processing Run Start Date: 16-Oct-2022 2:24 PM

Processing Run End Date: 16-Oct-2022 8:34 PM

Specified Dose Range (kGv):

25.0 - 40.0

Calculated Min Dose (kGy):

28.5

Reference Dose Range (kGy):

27.4 - 36.5

Calculated Max Dose (kGy):

35.0

PO Number: 403635

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

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 17-Oct-2022 9:26 AM

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 WO55277 will be used in finished batch Fmp22307 55253.

Rel Date: 13-Aug-2018

Document ID: 125294

## 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: Fmp22307 55253

Lucideon Sample Number: UK224366-28391

Lucideon Report Number: UK224366-28391/MFEP

Issue Number:

Date Logged:

09-Nov-2022

**Order Number:** 

403906

**Date Reported:** 

07-Dec-2022

Date(s) of Test(s):

15-Nov-2022 to 29-Nov-2022

**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 on Dec 22

**Senior Business Support Administrator** 

Mrs Natalie Boot

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