

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date:

14 June 2022

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429		
Batch Number	FMP22165	54507	
Production Date	14/06/2022		
Expiration Date	EXP 14/06/2024		

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	13.0	
Specific Gravity (20°C)	DM004	1.040	1.060	1.046	
Cationic Content	DM020	14.25	15.75	15.61	

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 2017

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

Prepared for:					
Gamma Process Run ID					
Product Code		Lot Number	Quantity	UOM	
C/SINALD BOTTLES/CAPS DV4894	BAGS	54518	16	Case	
Validation Referen	ice Number:	4894			
Processing Run Start Date: 28-May-2022 3:05 PM					
Processing Run End Date: 28-May-2022 9:12 PM					
Specified Dose Range	e (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.1	
Reference Dose Rang	le (kGy):	27.4 - 36.5	Calculated Max Dose (kGy):	36.5	

PO Number: 402391

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

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 29-May-2022 3:05 PM

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 WO54518 will be used in finished batch Fmp22165 54507.

**Olga Kirchner** 

Document ID: 113092

# PHARMACEUTICAL ANALYSIS REPORT



**Flexible Medical Packaging** Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Cleansinald SC

Sample Code: Fmp22165 54507 Sample Description:

13-Jul-2022

Lucideon Sample Number: UK222549-16273

Lucideon Report Number: UK222549-16273/MFEP Issue Number: 1 Date Logged: 22-Jun-2022

**Date Reported:** 

Order Number:

Date(s) of Test(s):

**Sterility Testing** Membrane Filtration EP 402814

24-Jun-2022 to 08-Jul-2022

#### **Test Results:**

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

**End of Test Report** 

13-JUI-22

Mrs Natalie Boot Senior Business Support Administrator

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