

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

### Date: 07 February 2023

Product Name	CLEA	CLEARKLENS CLEANSINALD SC VH9	
Product Code	7516430		
Batch Number	FMP23038	56048	
Production Date	07/02/2023		
Expiration Date	EXP 07/02/2025		

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	14.81

On behalf of Diversey site	Name:	Justyna Staron	Sabcho Svetoslavov
Quality Manger	Position	Quality Control Inspector	

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

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

FLEXIBLE MEDICAL PACKAGING LTD (8245) **Prepared for:** 2173-34519A Gamma Process Run ID Quantity UOM Lot Number **Product Code** 30 Case 56064 C/SINALD BOTTLES/CAPS/BAGS DV4894 Validation Reference Number: 4894 Processing Run Start Date: 27-Jan-2023 12:51 PM Processing Run End Date: 27-Jan-2023 7:08 PM Calculated Min Dose (kGy): 28.4 25.0 - 40.0 Specified Dose Range (kGy): 34.8 Calculated Max Dose (kGy): 27.4 - 36.5 **Reference Dose Range (kGy):** 

PO Number: 404384

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

Gamma Process Run Approval authorized by STERIS Date/Time E-Signed: 28-Jan-2023 6:29 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

Item irradiated under WO56064 will be used in finished batch Fmp23038 56048.

Olga Kirchner

Document ID: 134059

Page 1 of 1

# 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 Description: Sample Code: Fmp23038 56048

07-Mar-2023

Lucideon Sample Number: UK23513-3550

Lucideon Report Number: UK23513-3550/MFEP

Date Logged: 13-Feb-2023

Date Reported:

Order Number:

Date(s) of Test(s):

Sterility Testing Membrane Filtration EP

Issue Number:

404565

1

17-Feb-2023 to 07-Mar-2023

### **Test Results:**

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

**End of Test Report** 

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Mrs Natalie Boot Senior Business Support Administrator

Page 1 of 1

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