

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date:

13 July 2023

Product Name	CLEARKL	CLEARKLENS CLEANSINALD SC VH9		
Product Code	101107577			
Batch Number	FMP23194	58412		
Production Date	13/07/2023			
Expiration Date	EXP 13/07/2025			

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	12.6
Specific Gravity (20°C)	DM004	1.040	1.060	1.05
Cationic Content	DM020	14.25	15.75	15.49

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

Prepared for: Gamma Process Run ID	FLEXIBLE MEDICAL PACKAGING LTD (8245) 2173-38113A			
Product Code		Lot Number	Quantity	UOM
C/SINALD BOTTLES/CAPS DV4894	BAGS	57595	46	Case
Validation Referen	ce Number:	4894		
Processing Run Start Date: 16-Jun-2023 10:18 AM				
Processing Run End Date: 16-Jun-2023 10:10 PM				
Specified Dose Range	e (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.3
Reference Dose Rang	e (kGy):	27.4 - 36.5	Calculated Max Dose (kGy):	37.0

PO Number: 405509

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 17-Jun-2023 5:01 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 WO57595 will be used in finished batch Fmp23194 58412.

Olga Kirchner

Document ID: 147035

N/A

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: Fmp23194 58412

20-Jul-2023

09-Aug-2023

Lucideon Sample Number: UK232790-21038

Lucideon Report Number: UK232790-21038/MFEP

Issue Number: 1

Order Number:

Sterility Testing Membrane Filtration EP

Date(s) of Test(s):

405856

25-Jul-2023 to 08-Aug-2023

Test Results:

Date Logged:

Date Reported:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report



Senior Business Support Administrator	
Mrs Natalie Boot	

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