

Diversey Europe Operations BV Maarssenbroeksedijk 2 3642 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427 www.Diversey.com

CERTIFICATE OF ANALYSIS

Date:

18 March 2022

Product Name	CLEARKLENS CLEANSINALD SC VH9 7516429		
Product Code			
Batch Number	FMP22075	53879	
Production Date	16/03/2022		
Expiration Date	EXP 16/03/2024		

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	12.9
Specific Gravity (20°C)	DM004	1.040	1.060	1.048
Cationic Content	DM020	14.25	15.75	15.46

On behalf of Diversey site Quality Manger	Name:	Angelika Partynska Justyna Staron
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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 2173-25941A

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

C/SINALD BOTTLES/CAPS/BAGS WO53949 15 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 05-Feb-2022 4:59 AM

Processing Run End Date: 05-Feb-2022 10:47 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 27.5

Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 34.3

PO Number: 401865

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 05-Feb-2022 2:38 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 WO53949 will be used in finished batch FMP22075 53879.

Olga Kirchner

Document ID: 101883

N/A Last Revised in Rel 2.0.0.0 Rel Date: 13-Aug-2018 Page 1 of 1

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: FMP22075 53879

Lucideon Sample Number: UK221489-9432

Lucideon Report Number: UK221489-9432/MFEP

Issue Number:

1

Date Logged:

07-Apr-2022

Order Number:

402354

Date Reported:

03-May-2022

Date(s) of Test(s):

14-Apr-2022 to 28-Apr-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

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1