

Diversey Europe Operations BV Maarssenbroeksedlijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date:

25 October 2021

	CLEARKLENS CLEANSINALD SC VH9		
Product Name			
Product Code	7516429		
Batch Number	FMP21293	52617	
Production Date	20/10/2021		
Expiration Date	EXP 20/10/2023		

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	Limi Lower	- Upper	Results
Amnoronae	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
Appearance pH (neat solution)	DM001	12.0	13.0	12.6
Specific Gravity (20°C)	DM004	1.040	1.060	1.048
Cationic Content	DM020	14.25	15.75	15.65

On behalf of Diversey site Quality Manger	Name:	urszula Haraburda Justyna Staron
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

Date of issuing: November 24th 2017 Version: 02 COA Template

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-22094A

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

C/SINALD BOTTLES/CAPS/BAGS 52708 15 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 05-Sep-2021 12:51 AM
Processing Run End Date: 05-Sep-2021 11:04 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.7

Reference Dose Range (kGy): 27.4 - 36.5 Calculated Max Dose (kGy): 36.1

PO Number: 400751

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 05-Sep-2021 3:17 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 WO52708 will be used in finished batch FMP21293 52617.

Olga Kirchner

Rel Date: 13-Aug-2018

Document ID: 88239

Last Revised in Rel 2.0.0.0

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: Fmp21293 52617

Lucideon Sample Number: UK214671-30749

Lucideon Report Number: UK214671-30749/MFEP

Issue Number:

Date Logged:

02-Nov-2021

Order Number:

401191

Date Reported:

16-Dec-2021

Date(s) of Test(s):

02-Dec-2021 to 16-Dec-2021

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

NCBOOK 16-DEC-21

Mrs Natalie Boot

Senior Business Support Administrator

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested.