

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

## **CERTIFICATE OF ANALYSIS**

Date:

21 March 2022

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429		
Batch Number	FMP22080	54060	
Production Date	21/03/2022		
Expiration Date	EXP 21/03/2024		

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 Lower - Upper		Results	
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:	Justyna Staron Angelika Partynska
	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	2173-26109A					
Dreduct Code			Quantity			
Product Code		Lot Number	Quantity	<u>UOM</u>		
C/SINALD BOTTLES/CAPS DV4894	BAGS	WO54187	15	Case		
Validation Reference Number: 4894						
Processing Run Start Date: 13-Feb-2022 1:13 PM						
Processing Run End Date: 13-Feb-2022 6:57 PM						
Specified Dose Range	e (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.3		
Reference Dose Rang	le (kGy):	27.4 - 36.5	Calculated Max Dose (kGy):	35.6		

PO Number: 401922

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

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 13-Feb-2022 10:43 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 WO54187 will be used in finished batch FMP22080 54060.

Olga Kirchner

Document ID: 102558

# 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: FMP22080 54060

Lucideon Sample Number: UK221489-9426

 

 Lucideon Report Number:
 UK221489-9426/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 30-Apr-2022

 Sterility Testing Membrane Filtration EP
 Membrane Filtration EP
 Membrane Filtration EP
 1

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

**End of Test Report** 

N 03-N0Mrs Natalie Boot

Mirs Natalle Boot Senior Business Support Administrator

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

Lucideon Limited Queens Road, Penkhull Stoke-on-Trent Staffordshire ST4 7LQ T +44 (0)1782 764428 enquiries@lucideon.com www.lucideon.com

Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.