

Diversay Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utracht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 15 January 2020

Product Name	CLEARKLENS CLEANSINALD SC VH9	
Product Code	7516429	
Batch Number	FMP20015	49215
Production Date	15/01/2020	
Expiration Date	EXP 15/01/2022	

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	its - 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	1.052
Catonic content	DM020	14.25	15.75	14.51

On behalf of Diversey site Quality Manger	Name:	Angelika Partynska Urszula Haraburda
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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

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

#### Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-7121A

Product Code	Lot Number	Quantity	<u>UOM</u>
C/SINALD BOTTLES/CAPS/BAGS DV4894	WO48801	16	Case
Validation Reference Number: 4894			
Processing Run Start Date: 27-Dec-19	05:10 PM		
Processing Run End Date: 27-Dec-19	11:35 PM		
Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.1
Reference Dose Range (kGy):	27.4- 36.5	Calculated Max Dose (kGy):	35.1

PO Number: PO34486

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

#### **Signature Manifest**

#### Reviewed and E-Signed By: Bhavya Ramisetty (Quality Engineer)

Date/Time E-Signed: 2019-12-30 10:36 AM

Document Content Revision: 1

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 WO48801 will mbe used in finished batch Fmp20015 49215.

Olga Kirchner

# PHARMACEUTICAL ANALYSIS REPORT



#### Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO:	Mrs.Olga	Kirchner
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Report of Tests on: Cleansinald SC

Sample Description: Sample Code: Fmp20015 49215

12-Mar-2020

Lucideon Sample Number: UK20478-3786

Lucideon Report Number: UK20478-3786/MFEP

Date Logged: 31-Jan-2020

Date Reported:

Order Number:

Issue Number:

Date(s) of Test(s): <u>Sterility Testing</u> Membrane Filtration EP PO 34687

1

16-Feb-2020 to 03-Mar-2020

#### **Test Results:**

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

Joboot 12 Mar-20

Mrs Natalie Boot Senior Business Support Assistant

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