

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date:

08 January 2020

Product Name	CLEARKLENS CLEANSINALD SC VH9 7516429		
Product Code			
Batch Number	FMP20008	49153	
Production Date	08/01/2020		
Expiration Date	EXP 08/01/2022		

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	12.8
Specific Gravity (20°C)	DM004	1.040	1.060	1.056
Catonic content	DM020	14.25	15.75	14.51

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

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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: 2173-6237A

**Product Code Lot Number** C/SINALD BOTTLES/CAPS/BAGS

**DV4894** 

Validation Reference Number:

Processing Run Start Date: 21-Nov-19 06:46 PM

Processing Run End Date: 22-Nov-19 01:04 AM

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

WO48707

Reference Dose Range (kGy): 27.4-36.5 Calculated Max Dose (kGy): 36.3

PO Number: PO34291

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

## **Signature Manifest**

Reviewed and E-Signed By: Kristen Middleton (Quality Manager)

Date/Time E-Signed: 2019-11-22 08:55 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 WO48707 will be used in finished batch Fmp20008 49153

Olga Kirchner

Quantity

**UOM** 

Case

Document ID: 35588

Rei Date: 08/13/2018

## PHARMACEUTICAL ANALYSIS REPORT



Fiexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO: Miss Caroline Pascoe

Report of Tests on:

Cleansinald SC

Sample Description:

Sample Code: Fmp20008 49153

Lucideon Sample Number: UK20249-2279

Lucideon Report Number: UK20249-2279/MFEP

Issue Number:

Date Logged:

17-Jan-2020

**Order Number:** 

PO34594

**Date Reported:** 

06-Feb-2020

Date(s) of Test(s):

21-Jan-2020 to 04-Feb-2020

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** 



Senior Business Support Assistant