

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

# Date: 01.10.2019

Product Name	CLEARKLENS CLEANSINALD SS VH9S			
Product Code	100 84 82,54			
Batch Number	FNP19274, 48044			
Production Date	01.10.2019			
Expiration Date	Exp OLOLIZON			

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 Clear Slightly Yellow Liquid		Results
Appearance	Visual			Clean slighty
pH (neat solution)	DM001	9.0	11.4	0.8
Specific Gravity (20°C)	DM004	0.990	1.010	0.995

On behalf of Diversey site	Name :	Istaun Particesto
Quality Manager	Position	Quality Control Inspector

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

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

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

Gamma Process Run ID: 2173-4851A

Product Code	Lot Number	Quantity	UOM		
C/SINALD SS 900ml Bottle DV4673 WO48045 11 Case Validation Reference Number: 4673					
Processing Run Start Date: 26-Aug-19 07:11 AM					
Processing Run End Date: 26-Aug-19 01:32 PM					
Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.7		
Reference Dose Range (kGy):	27.3- 36.6	Calculated Max Dose (kGy):	35.6		

## Gamma Process Run Approval authorized by STERIS

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 WO48045 will be used in finished batch Fmp19274 48044

Olga Kirchner

# 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 SS				
Sample Description:	Sample Code: FMP19274 48044				
Lucideon Sample Number:	(195535)-42392				
Lucideon Report Number:	(195535)-42392/MFEP	Issue Number:	1		
Date Logged:	07-Oct-2019	Order Number:	34035		
Date Reported:	08-Nov-2019	Date(s) of Test(s):	25-Oct-2019	to	08-Nov-2019
<u>Sterility Testing</u> 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** 

NCBOT 08-NOV-19 Mrs Natalie Boot

### Senior Business Support Assistant

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