

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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# **CERTIFICATE OF ANALYSIS**

Date: 18.09.2019

Product Name	CLEARKLENS CLEANSINALD SS VH9S		
Product Code			
Batch Number	FMP 19260 47924		
Production Date	17/09/2019		
<b>Expiration Date</b>	EXP 17/03/2021		

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		Results	
		Lower -	Upper		
Appearance	Visual	Clear Slightly Yellow Liquid		Jellou byou	
pH (neat solution)	DM001	9.0	11.4	FOI	
Specific Gravity (20°C)	DM004	0.990	1.010	0.996	

On behalf of Diversey site	Name:	Maralenda Poutyerst
Quality Manager	Position	Quality Control Inspector

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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: 2173-4850A

**Product Code Lot Number** Quantity UOM WO47932 11 C/SINALD SS 900ml Bottle DV4673 Case

**Validation Reference Number:** 4673

Processing Run Start Date: 26-Aug-19 06:56 AM Processing Run End Date: 26-Aug-19 01:18 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.1

35.1 Reference Dose Range (kGy): 27.3-36.6 Calculated Max Dose (kGy):

### 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 WO47932 will be used in finished batch Fmp19260 47924.

Olga Kirchner

Document ID: 27438

Rel Date: 08/13/2018

Last Revised in Rel 2.0.0.0

# 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: FMP19260 47924

Lucideon Sample Number: (195218)-40477

Lucideon Report Number: (195218)-40477/MFEP

Issue Number:

Date Logged:

20-Sep-2019

Order Number:

PO33940

**Date Reported:** 

08-Nov-2019

Date(s) of Test(s):

25-Oct-2019 to 08-Nov-2019

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** 

NOBOOK 08-NOV-19

Senior Business Support Assistant