

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

# **CERTIFICATE OF ANALYSIS**

Date: 11 2020

Product Name	CLEARKLENS CLEANSINALD SS VH9S			
Product Code				
Batch Number	FMP20316 51141			
Production Date	111112020			
Expiration Date	EXP 11 05 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	Limits Lower - Upper Clear Slightly Yellow Liquid		Results	
Appearance pH (neat solution)	Visual			Clear slightly	
	DM001	9.0	11.4	10.9	
Specific Gravity (20°C)	DM004	0.990	1.010	0.997	

On behalf of Diversey site Quality Manager	Name:	U. Maraburda, A. Bons
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

n : 02 Date of issuing : Nove	nber 24 2017
	on : 02 Date of issuing : Noven

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

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-13462A

Product CodeLot NumberQuantityUOMC/SINALD SS 900ml Bottle DV4673WO5059213 Case

Validation Reference Number: 4673

Processing Run Start Date: 15-Sep-20 04:34 AM

Processing Run End Date: 15-Sep-20 10:30 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 30.1

Reference Dose Range (kGy): 27.3-36.6 Calculated Max Dose (kGy): 36.4

PO Number: 36337

## 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 WO50592 will be used in finished batch Fmp20316 51141.

Olga Kirchner

Document ID: 60109

Last Revised in Rel 2.0.0.0

Rel Date: 08/13/2018 Page 1 of 1

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Cleansinald SS

Sample Description:

Sample Code: Fmp20316 51141

Lucideon Sample Number: UK204692-32666

Lucideon Report Number: UK204692-32666/MFEP

Issue Number:

Date Logged:

17-Nov-2020

Order Number:

PO 36828

**Date Reported:** 

08-Dec-2020

Date(s) of Test(s):

20-Nov-2020 to 04-Dec-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** 



Mrs Andrea Saunders

**Business Support Assistant**