

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

## **CERTIFICATE OF ANALYSIS**

Date: 23 November 2022

CLEARKLENS CLEANSINALD SC VH9		
7516429		
FMP22325 55348		
21/11/2022		
EXP 21/11/2024		

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	Limits		Results
-	Method	Lower -	- Upper	
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	1.048
Cationic content	DM020	14.25	15.75	15.64

	Name:	Edyta Rodrígues Angelíka Partynska
On behalf of Diversey site  Quality Manager	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

	, and a significant	
COA Template	Version : 04	Date of issuing: March 11th 2019

## STERIS: Gamma Certificate Of Processing

Prepared for:

**FLEXIBLE MEDICAL PACKAGING LTD (8245)** 

Gamma Process Run ID

2173-32095A

**Product Code** 

Lot Number

Quantity

C/SINALD BOTTLES/CAPS/BAGS

DV4894

55371

16 Case

Validation Reference Number:

4894

**UOM** 

Processing Run Start Date: 23-Oct-2022 2:52 AM

Processing Run End Date: 23-Oct-2022 9:04 AM

Specified Dose Range (kGy):

25.0 - 40.0

Calculated Min Dose (kGy):

27.8

Reference Dose Range (kGy):

27.4 - 36.5

Calculated Max Dose (kGy):

34.1

PO Number: 403728

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

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 23-Oct-2022 7:59 PM

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 WO55371 will be used in finished batch Fmp22325 55348.

Olga Kirchner

Document ID: 125797

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Cleansinald SC

Sample Description:

`Sample Code: Fmp22325 55348

Lucideon Sample Number: UK224668-30340

Lucideon Report Number: UK224668-30340/MFEP

Issue Number:

Date Logged:

29-Nov-2022

Order Number:

404057

**Date Reported:** 

09-Jan-2023

Date(s) of Test(s):

22-Dec-2022 to 09-Jan-2023

**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** 

09 JAN 23 Miss Rosie Jones

**Pharmaceutical Microbiology Manager** 

Page 1 of 1