

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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# **CERTIFICATE OF ANALYSIS**

## Date: 14.09.2020

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code			
Batch Number	THP 20258, 50314		
Production Date	14.09 2022		
Expiration Date	EXP 4109 2012		

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 Liqui	·	Clear Slightly	
pH (neat solution)	DM001	12.0	13.0	1 2.7	
Specific Gravity (20°C)	DM004	1.040	1.060	1.048	
Cationic content	DM020	14.25	15.75	15.52	

On behalf of Diversey site Quality Manager	Name :	J. Stavou, A. Borys
	Position	Quality Control Inspector

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COA Template Version : 02 Date of issuing : November 24<sup>th</sup> 2017

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

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

Gamma Process Run ID: 2173-13169A

Product Code	Lot Number	Quantity	<u>UOM</u>							
C/SINALD BOTTLES/CAPS/BAGS DV4894	WO50313 16		Case							
Validation Reference Number: 4894										
Processing Run Start Date: 28-Aug-20 06:06 PM										
Processing Run End Date: 29-Aug-20	12:14 AM									
Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy): 29.6								
Reference Dose Range (kGy):	27.4- 36.5	Calculated Max Dose (kGy): 37.6								

PO Number: 36273

## 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 WO50313 will be used in finished batch Fmp20258 50314.

Olga Kirchner

# PHARMACEUTICAL ANALYSIS REPORT

12-Oct-2020



Flexible Medical Packaging Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on:Cleansinald SCSample Description:Sample Code: Fmp20258 50314Lucideon Sample Number:UK203860-27116Lucideon Report Number:UK203860-27116/MFEPIssue Number:1

Date Logged: 23-Sep-2020

Date Reported:

Order Number: Date(s) of Test(s):

Sterility Testing

Membrane Filtration EP

PO36443

25-Sep-2020 to 09-Oct-2020

#### **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 12-001-20

### Mrs Natalie Boot Senior Business Support Assistant

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