

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 17 November 2022

Product Name	CLEARKLENS CLEANSINALD SS VH9S	CLEARKLENS CLEANSINALD SS VH9S		
<b>Product Code</b>	100848254			
Batch Number	FMP22321 55737			
<b>Production Date</b>	17/11/2022			
<b>Expiration Date</b>	17/05/2024			

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	<b>Test Method</b>	Limi	ts	Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	9.0	11.4	10.79
Specific Gravity (20°C)	DM004	0.990	1.010	0.997

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

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COA Template	Version: 02	Date of issuing: November 24th 201	7

# STERIS: Gamma Certificate Of Processing

Prepared for:

**FLEXIBLE MEDICAL PACKAGING LTD (8245)** 

Gamma Process Run ID

2173-32094A

**Product Code** 

**Lot Number** 

Quantity

C/SINALD SS 900ml Bottle DV4673

55812

Casa

UOM

Validation Reference Number:

Processing Run Start Date: 22-Oct-2022 10:37 PM

Processing Run End Date: 23-Oct-2022 5:14 AM

Calculated Min Dose (kGy):

29.0

Specified Dose Range (kGy): Reference Dose Range (kGy): 25.0 - 40.0 27.3 - 36.6

Calculated Max Dose (kGy):

35.2

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 7:15 AM

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 WO55812 will be used in finished batch Fmp22321 55737.

Olga Kirchner

Document ID: 125784

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Clenasinald SS

Sample Description:

Sample Code: 22321 55737

Lucideon Sample Number: UK224572-29721

Lucideon Report Number: UK224572-29721/MFEP Issue Number:

Date Logged:

22-Nov-2022

**Order Number:** 

PO 403993

Date Reported:

14-Dec-2022

Date(s) of Test(s):

30-Nov-2022 to 14-Dec-2022

**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** 

BOOK IL-DEC-22

Mrs Natalie Boot

Senior Business Support Administrator

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