

Diversey Europe BV Maarssenbroeksedlijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 26 (10/2020

Product Name	CLEARKLENS CLEANSINALD SS VH9S		
Product Code			
Batch Number	THP20300 50976		
Production Date	261012020		
Expiration Date	EXP 26 [04] 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		Results
		Lower -	- Upper	
Appearance	Visual	Clear Slightly Yellow Liquid		Clear slightly
pH (neat solution)	DM001	9.0	11.4	10.6
Specific Gravity (20°C)	DM004	0.990	1.010	0997

On behalf of Diversey site Quality Manager	Name:	Mardanda A. Bons
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of issuing: November 24 2017
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-13873A

Product Code Lot Number Quantity UOM

C/SINALD SS 900ml Bottle DV4673 WO50344 13 Case

Validation Reference Number: 4673

Processing Run Start Date: 03-Oct-20 02:55 AM

Processing Run End Date: 03-Oct-20 08:26 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.5

Reference Dose Range (kGy): 27.3 - 36.6 Calculated Max Dose (kGy): 36.0

PO Number: 36453

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 WO50344 will be used in finished batch Fmp20300 50976.

Olga Kirchner

Rel Date: 08/13/2018

Document ID: 61462

Last Revised in Rel 2.0.0.0

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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: Fmp20300 50976

Lucideon Sample Number: UK204489-31980

Lucideon Report Number: UK204489-31980/MFEP

Issue Number:

Date Logged:

03-Nov-2020

Order Number:

PO 36712

Date Reported:

01-Dec-2020

Date(s) of Test(s):

13-Nov-2020 to 27-Nov-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