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CERTIFICATE OF ANALYSIS

Date:

21 May 2020

Product Name	CLEARKLENS CLEANSINALD SS VH9S		
Product Code	100848254		
Batch Number	FMP20142	49634	
Production Date	21/05/2020		
Expiration Date	EXP 21/11/2021		

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 Yellow Liquid
pH (neat solution)	DM001	9.0	11.4	10.4
Specific Gravity (20°C)	DM004	0.990	1.010	0.997

On behalf of Diversey site Quality Manger	Name:	urszula Haraburda Angelika Partynska
	Position	Quality Control Inspector

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-10244A

Product CodeLot NumberQuantityUOMC/SINALD SS 900ml Bottle DV4673WO4963511 Case

Validation Reference Number: 4673

Processing Run Start Date: 05-May-20 04:09 PM

Processing Run End Date: 05-May-20 09:38 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 30.2

Reference Dose Range (kGy): 27.3-36.6 Calculated Max Dose (kGy): 36.3

PO Number: 35340

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 WO49635 will be used in finished batch Fmp20142 49634.

Olga Kirchner

Rel Date: 08/13/2018

Document ID: 49846

Last Revised in Rel 2.0.0.0

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Cleansinlad SS

Sample Description:

Sample Code: Fmp20142 49634

Lucideon Sample Number: UK202327-16970

Lucideon Report Number: UK202327-16970/MFEP

Issue Number:

Date Logged:

05-Jun-2020

Order Number:

PO35608

Date Reported:

26-Jun-2020

Date(s) of Test(s):

08-Jun-2020 to 22-Jun-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

NOBOOK 26-JUN-20

Mrs Natalie Boot

Senior Business Support Assistant