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CERTIFICATE OF ANALYSIS

Date: 05 September 2019

Product Name	CLEARKLE	CLEARKLENS CLEANSINALD SC VH9		
Product Code	7516429			
Batch Number	FMP19248	48413		
Production Date	05/09/2019			
Expiration Date	EXP 05/09/2021			

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	Lim	its	Results
		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	1.055

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

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COA Template	Version: 02	Date of issuing: November 24th
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PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO: Mrs.Oiga Kirchner

Report of Tests on: Cleansinald SC

Sample Description: Sample Code: FMP19248 48413

Lucideon Sample Number: (195132)-39891

Lucideon Report Number: (195132)-39891/MFEP Issue Number:

Date Logged: Order Number: 16-Sep-2019 PO 33882

03-Jan-2020 Date(s) of Test(s): 23-Nov-2019 to 03-Jan-2020 **Date Reported:**

> 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 Natalle Boot

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4747A

Product Code Lot Number Quantity UOM

C/SINALD BOTTLES/CAPS/BAGS

WO47641

11 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 25-Aug-19 06:58 PM

Processing Run End Date: 26-Aug-19 01:24 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 29.8

Reference Dose Range (kGy): 27.4- 36.5 Calculated Max Dose (kGy): 37.0

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 umder WO47641 will be used in finished batch FMP19248 48413.

Olga Kirchner

Document ID: 27389

Rel Date: 08/13/2018