

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427 www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 10 March 2020

Product Name	CLEARKLEI	NS CLEANSINALD SS VH9S
Product Code	100848254	
Batch Number	FMP20069	49172
Production Date	09/03/2020	
Expiration Date	EXP 09/09/2021	

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	Limits Lower - Upper		Results	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid	
pH (neat solution)	DM001	9.0	11.4	10.1	
Specific Gravity (20°C)	DM004	0.990	1.010	0.997	

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

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COA lempidie version. 02 Dure of issoing . November 2411	COA Template	Version : 02	Date of issuing : November 24th
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-8347A

Product Code	Lot Number	Quantity	UOM			
C/SINALD SS 900ml Bottle DV4673 Validation Reference Number:	WO49157 4673	12	Case			
Processing Run Start Date: 20-Feb-20 01:13 AM						
Processing Run End Date: 20-Feb-20 06:42 AM						
Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	27.5			
Reference Dose Range (kGy):	27.3- 36.6	Calculated Max Dose (kGy):	35.2			

PO Number: 34761

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 WO49157 will be used in finished batch Fmp20069 49172.

Olga Kirchner

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS				
FAO: Mrs.Olga Kirchner				
Report of Tests on:	Cleansinald SS			
Sample Description:	Sample Code: Fmp20069	49172		
Lucideon Sample Number:	UK201296-10111			
Lucideon Report Number:	UK201296-10111/MFEP	Issue Number:	1	
Date Logged:	16-Mar-2020	Order Number:	PO34979	
Date Reported:		Date(s) of Test(s): rility Testing ane Filtration EP	21-Mar-2020	to 04-Apr-2020
Test Results:				
Result: Pass				
The test results meet the EP/US	P criteria: Yes			

Tests carried out in accordance with cGMP

End of Test Report

reg 06 APR 20

Mrs Andrea Saunders Business Support Assistant

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Lucideon Limited Queens Road, Penkhull Stoke-on-Trent Staffordshire ST4 7LQ T +44 (0)1782 764428 enquiries@lucideon.com www.lucideon.com

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