

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 01.10.2019

Product Name	CLEARKLENS CLEANSINALD SS VH9S			
Product Code	100 84 82,54			
Batch Number	FNP19274, 48044			
Production Date	01.10.2019			
Expiration Date	Exp OLOLIZON			

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 Clear Slightly Yellow Liquid		Results
Appearance	Visual			Clean slighty
pH (neat solution)	DM001	9.0	11.4	0.8
Specific Gravity (20°C)	DM004	0.990	1.010	0.995

On behalf of Diversey site	Name :	Istaun Particesto
Quality Manager	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24th 2017		
		ZOI/		

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4851A

Product Code	Lot Number	Quantity	UOM		
C/SINALD SS 900ml Bottle DV4673 WO48045 11 Case Validation Reference Number: 4673					
Processing Run Start Date: 26-Aug-19 07:11 AM					
Processing Run End Date: 26-Aug-19 01:32 PM					
Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.7		
Reference Dose Range (kGy):	27.3- 36.6	Calculated Max Dose (kGy):	35.6		

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 WO48045 will be used in finished batch Fmp19274 48044

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: FMP19274 48044				
Lucideon Sample Number:	(195535)-42392				
Lucideon Report Number:	(195535)-42392/MFEP	Issue Number:	1		
Date Logged:	07-Oct-2019	Order Number:	34035		
Date Reported:	08-Nov-2019	Date(s) of Test(s):	25-Oct-2019	to	08-Nov-2019
<u>Sterility Testing</u> 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

NCBOT 08-NOV-19 Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

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

Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.