

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 26/11/2019

Product Name	CLEARKLENS CLEANSINALD SC VH9		
Product Code	75161.29		
Batch Number	FMPIQ320 LELIS		
Production Date	26/11/2019		
Expiration Date	EXP 261112021		

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	Lin Lower -	nits Upper	Results
Appearance	Visual	Clear Sligh		Clear Slightly Yellas Liquid
pH (neat solution)	DM001	12.0	13.0	20
Specific Gravity (20°C)	DM004	1.040	1.060	1.052
Cationic content	DM020	14.25	15.75	14 51

Quality Manager	Position	Quality Control Inspector	
On behalf of Diversey site	Name :	Navaburda J. Stanon	

This document being issued electronically does not bear a signature

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4746A

Product Code	Lot Number	Quantity	UOM						
C/SINALD BOTTLES/CAPS/BAGS DV4894	WO47643	11	Case						
Validation Reference Number: 4894									
Processing Run Start Date: 25-Aug-19	06:46 PM								
Processing Run End Date: 26-Aug-19	01:08 AM								
Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy): 2							
Reference Dose Range (kGy):	27.4- 36.5	Calculated Max Dose (kGy):	36.4						

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 WO47643 will be used in finished batch Fmp19330 48415.

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 SC

Sample Description: Sample Code: Fmp 19330 48415

03-Jan-2020

Lucideon Sample Number: (196493)-49584

Lucideon Report Number: (196493)-49584/MFEP

Date Logged: 29-Nov-2019

Date Reported:

Order Number:

Date(s) of Test(s):

Sterility Testing Membrane Filtration EP

Issue Number:

PO 34383

1

01-Dec-2019 to 03-Jan-2020

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

NOBOOL 03-JON-20

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.