

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date:

10 August 2023

Product Name	CLEARKLENS CLEANSINALD SC VH9	
Product Code	101107577	
Batch Number	FMP23222 57857	
Production Date	10/08/2023	
Expiration Date	EXP 10/08/2025	

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	12.5
Specific Gravity (20°C)	DM004	1.040	1.060	1.048
Cationic Content	DM020	14.25	15.75	15.49

On behalf of Diversey site	Name:	Edyta Rodrígues Sabcho Svetoslavov
Quality Manger	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template Version : 04 Date of issuing : March 11th 2019			
	COA Template	Version : 04	Date of issuing : March 11th 2019

STERIS: Gamma Certificate Of Processing

Prepared for:	FLEXIBLE M	EDICAL PACKAGI	NG LTD (8245)	
Gamma Process Run ID	2173-39039A			
Product Code		Lot Number	Quantity	<u>UOM</u>
C/SINALD BOTTLES/CAPS DV4894	S/BAGS	57860	16	Case
Validation Referer	nce Number:	4894		
Processing Run Start Date	e: 20-Jul-2023 §):37 PM		
Processing Run End Date:	: 21-Jul-2023 4	1:11 AM		
Specified Dose Range	e (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	30.6
Reference Dose Rang	ge (kGy):	27.4 - 36.5	Calculated Max Dose (kGy):	37.5

All dosimeters measured within the required reference dose range to meet Customer dose specification.

PO Number: 405817

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest
Reviewed and E-Signed By: Tamas Szatmari (Quality Engineer)
Date/Time E-Signed: 24-Jul-2023 10:52 AM
Document Content Revision: 1

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 WO57860 will be used in finished batch Fmp23222 57857.

Olga Kirchner

Document ID: 150539

N/A

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: Fmp23222 57857

Lucideon Sample Number: UK233130-23565

Lucideon Report Number:	UK233130-23565/MFEP	Issue Number:	1
Date Logged:	17-Aug-2023	Order Number:	406090
Date Reported:	06-Sep-2023	Date(s) of Test(s):	22-Aug-2023 to 05-Sep-2023
		erility Testing	
	Memb	rane 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



Natalie Boot

Signer Name: Natalie Boot Signing Reason: I have reviewed this document Signing Time: 06 September 2023 | 11:07 BST

-90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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