

Diversey Europe Opertaions BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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# CERTIFICATE OF ANALYSIS

## Date: 09.09.2019

Product Name	CLEARKLENS CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FMP 19252, 47+21
Production Date	09 09 2019
Expiration Date	EXP 09 09 202

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			Clear slighty
pH (neat solution)	DM001	12.0	13.0	13.0
Specific Gravity (20°C)	DM004	1.040	1.060	1.055

	Name :	Y. Hauge Patjusts
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector

This document being issued	electronically does not bear a signature	
COA Template	Version : 02	Date of issuing : November 24" 2017
COA remplate		

### **STERIS: Gamma Certificate Of Processing**

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4748A

Lot Number	Quantity	<u>UOM</u>					
WO47722	11	Case					
Validation Reference Number: 4894							
Processing Run Start Date: 25-Aug-19 07:16 PM							
01:37 AM							
25.0 - 40.0	Calculated Min Dose (kGy):	30.3					
27.4- 36.5	Calculated Max Dose (kGy):	37.6					
	WO47722 4894 07:16 PM 01:37 AM 25.0 - 40.0	WO47722 11   4894 11   07:16 PM 11   01:37 AM 25.0 - 40.0   Calculated Min Dose (kGy): 11					

#### 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 WO47722 will be used in finished batch FMP19252 47721

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 SCSample Description:Sample Code: FMP19252 47721

Lucideon Sample Number: (195132)-39888

Lucideon Report Number:(195132)-39888/MFEPIssue Number:1Date Logged:16-Sep-2019Order Number:PO 33882Date Reported:03-Jan-2020Date(s) of Test(s):21-Nov-2019 to 03-Jan-2020Sterility Testing<br/>Membrane Filtration EPMembrane Filtration EPMembrane 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** 

NCBOOK 03-JON-20

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