

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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# **CERTIFICATE OF ANALYSIS**

### Date: 07 December 2023

Product Name	CLEAR	KLENS CLEANSINALD SS VH9S
Product Code	101109104	
Batch Number	FMP23341	59242
Production Date	07/12/2023	
Expiration Date	EXP 07/06/2025	

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	Limi Lower	its - Upper	Results
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
pH (neat solution)	DM001	9.0	11.4	10.9
Specific Gravity (20°C)	DM004	0.990	1.010	0.996

On behalf of Diversey site	Name:	Justyna Staron Angelíka Píetraszko
Quality Manger	Position	Quality Control Inspector

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COA Template Version : 04 Date of issuing : March 11th 2019			
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## **STERIS: Gamma Certificate Of Processing**

•	KIBLE MEDICAL PACKAGI -42493A	NG LTD (8245)	
Product Code	Lot Number	Quantity	UOM
C/SINALD SS 900ml Bottle DV467	73 59253- STR00	2250 5	Case
Validation Reference Nur	<b>nber:</b> 4673		
Processing Run Start Date: 25-No	ov-2023 6:15 AM		
Processing Run End Date: 25-No	ov-2023 1:08 PM		
Specified Dose Range (kGy	/): 25.0 - 40.0	Calculated Min Dose (kGy):	29.9
Reference Dose Range (kG	y): 27.3 - 36.6	Calculated Max Dose (kGy):	36.4

PO Number: 406932

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

## Gamma Process Run Approval authorized by STERIS

Date/Time: 25-Nov-2023 4:37 PM

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 WO59253 will be used in finish batch FMP23341 59242.

Olga Kirchner

Document ID: 161385

N/A

# PHARMACEUTICAL ANALYSIS REPORT



#### Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

		<u>rility Testing</u> rane Filtration EP			
Date Reported:	19-Jan-2024	Date(s) of Test(s):	04-Jan-2024	to	18-Jan-2024
Date Logged:	11-Dec-2023	Order Number:	407053		
Lucideon Report Number:	UK234537-34465/MFEP	Issue Number:	1		
Lucideon Sample Number:	UK234537-34465				
Sample Description:	Sample Code: Fmp23341	59242			
Report of Tests on:	Cleansinald SS				
FAO: Mrs. Olga Kirchner					

#### **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: 19 January 2024 | 12:28 GMT

90369E9048134123B65D5E8FBD375BF3

#### Mrs Natalie Boot

#### Senior Business Support Administrator

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