

**Tel. +31 (0)30 247 6427**

## CERTIFICATE OF ANALYSIS

Date: 1/4/16

<b>Product Name</b>	CLEARKLENS CLEANSINALD SS VH9S
<b>Product Code</b>	100848254
<b>Batch Number</b>	FMP16092 39998
<b>Production Date</b>	01/04/2016
<b>Expiration Date</b>	EXP 01/10/2017

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		Results
		Lower	Upper	
Appearance	Visual	Clear	Slightly Yellow Liquid	clear slightly yellow liquid
pH (100% 20°C)	JDM001	9.0	11.4	11.0
Specific Gravity (20°C)	JDM004	0.990	1.010	0.999

On behalf of Diversey site Quality Manager	Name :	C. P. P. Paul
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

COA 7516432	Version : 05	Date of issuing : April 27 <sup>th</sup> 2012
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 16-Feb-2016

UK32S11562543-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products

EN ISO 9001:2008 Quality Management System

EN ISO 13485:2012 Quality System - Medical Devices

Flexible Medical Packaging Ltd  
Unit 8, White Cross Ind Estate  
Hightown  
Lancaster  
Lancashire LA1 4XS  
UNITED KINGDOM

All in accordance with current Technical Agreement

## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1002720
Customer Reference Number:	P025956
Product Description:	C/SINALD SS 900ml BOTTLE 25-40kGy
Validation Reference:	4.1909
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	FMP BATCH NO: WO40025 THURS 11TH FEB 2016 1 PLT LOT 2

## Irradiation Data

Date and Time of Irradiation:	16-Feb-2016 01:34
Reference Dose Range kGy:	33.1 - 33.7
Calculated Minimum Dose kGy:	28.9
Calculated Maximum Dose kGy:	36.1

Items Irradiated under WO40025 will be used in finished product number: FMP16092 39998

*L. Gaugim. 07.04.2016.*

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069



# Wickham Laboratories

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Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 07 Apr 2016  
**Date Tested:** 13 Apr 2016  
**Date Test Completed:** 27 Apr 2016  
**Purchase Order:** 26320

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0028265/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 07/04/2016  
**Test Article:** ClearKlens Cleansinald SS  
**Sample Code:** FMP16092 39998  
**Batch Ref:** 7447  
**Qty Received:** 20 x 900mL Bottles

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	See external comments
Product Standard Data Sheet	FG047/psd	FM06

### Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name and position is shown below.

Date: 28 Apr 2016 13:24:48

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology