



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 29.11.2017

Product Name	CLEARKLENS CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FMP17331 44485
Production Date	27/11/2017
Expiration Date	EXP 27/11/2019

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	12.0	13.0	12.0
Specific Gravity (20°C)	JDM004	1.040	1.060	1.048

On behalf of Diversey site Quality Manager	Name :	J. Stauon, P. Tylus
	Position	Quality Control Inspector

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

COA 7516429	Version : 04	Date of issuing : April 27 <sup>th</sup> 2012
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# Wickham Laboratories

Contract Analytical Services

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

**Date Received:** 07 Dec 2017  
**Date Tested:** 08 Jan 2018  
**Date Test Completed:** 22 Jan 2018  
**Purchase Order:** 30093

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0039663/2  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 07/12/2017  
**Test Article:** ClearKlens Cleansinald SC  
**Sample Code:** FMP17331 44485  
**Batch Ref:** 585526  
**Qty Received:** 20 x 25mL 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 25 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM06

### Comments

0039663/2A  
4 x 25mL replacement bottles received 22/12/17 at 10:38. Sample Code: FMP17331 44485, Batch Number: 585526.

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

CBIO: MMSB

Date: 24 Jan 2018 11:11:32

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 22-Nov-2017

UK33S12007812-2-1

This is to certify that AST Daventry 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

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## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1111497
Customer Reference Number:	P029942
Product Description:	C/SINALD BOTTLES/CAPS/BAGS DV4894 25-40KGS
Validation Reference:	4894
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	W043814, 2 PLTS

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## Irradiation Data

Date and Time of Irradiation:	22-Nov-2017 03:08
Reference Dose Range kGy:	33.0 - 34.4
Calculated Minimum Dose kGy:	30.1
Calculated Maximum Dose kGy:	37.7

Items irradiated under W043814, will be used in finished product batch FMP17331 44485

*C Pascoe*

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**Irradiation Release Authorised By Synergy Health plc**

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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