



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427  
www.Diversey.com

## CERTIFICATE OF ANALYSIS

Date: 24.10.2018

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP18297 45538
Production Date	24/10/2018
Expiration Date	EXP 24/10/2020

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 Colourless Liquid		clear colourless liquid
pH (neat solution)	DM001	9.0	12.5	11.8
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	162 ppm.

On behalf of Diversey site Quality Manager	Name :	Naraburda, J. Stanon
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 <sup>th</sup> 2017
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## CERTIFICATE OF ANALYSIS

Date: 24.10.2018

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP18297 45538
Production Date	24/10/2018
Expiration Date	EXP 24/10/2020

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 Colourless Liquid		clear colourless liquid
pH (neat solution)	DM001	1.5	2.5	1.7
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	J. Slawon, Haverbude
	Position	Quality Control Inspector

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# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
Telephone: +44(0)1329 226600  
Fax: +44(0)1329 226688

mail@wickhamlabs.co.uk  
www.wickhamlabs.co.uk

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

**Date Received:** 07 Nov 2018  
**Date Tested:** 14 Nov 2018  
**Date Test Completed:** 28 Nov 2018  
**Purchase Order:** PO32052

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0045675/2  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 07/11/2018  
**Test Article:** Bi-Spore Base  
**Sample Code:** FMP18297 45538  
**Batch Ref:** 610100  
**Qty Received:** 20 x 100mL 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 two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM05-01

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

CBiof MKSB

Date: 29 Nov 2018 14:35:13

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



# Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd  
Hoeford Point, Barwell Lane, Gosport  
Hampshire PO13 0AU England  
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LA1 4XS

**Date Received:** 07 Nov 2018  
**Date Tested:** 14 Nov 2018  
**Date Test Completed:** 28 Nov 2018  
**Purchase Order:** PO32052

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0045675/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 07/11/2018  
**Test Article:** Bi-Spore Activator  
**Sample Code:** FMP18297 45538  
**Batch Ref:** 610101  
**Qty Received:** 20 x 100mL 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 two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM04-01

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

CBiol MR5B

Date: 29 Nov 2018 14:35:13

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

<http://www.steris-ast.com>

## Certificate of Irradiation

Date Issued: 15-Oct-2018

UK33S12181434-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 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:	1106825
Customer Reference Number:	P031884
Product Description:	BI-SP B3 COMPONENTS DV4725 25-40kGy
Validation Reference:	4725
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO45545, 1 PLT

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### Irradiation Data

Date and Time of Irradiation:	15-Oct-2018 05:50
Reference Dose Range kGy:	32.5 - 32.7
Calculated Minimum Dose kGy:	26.9
Calculated Maximum Dose kGy:	33.4

Items irradiated under WO45545, will be used in finished product batch FMP18297 45538

*C Pascoe*

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Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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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