

First off



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 08 09 2017

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP17251 / 43366
Production Date	08/09/2017
Expiration Date	EXP 08/09/2019

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 Colourless Liquid		clear colourless liquid
pH (100% 20°C)	JDM001	9.0	12.5	11.9
Specific Gravity (20°C)	JDM004	1.004	1.020	1.008
Potential Chlorine Dioxide		100	180	148.5 ppm

On behalf of Diversey site Quality Manager	Name :	Patyisko, J. Stawn
	Position	Quality Control Inspector

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

COA 7514852	Version : 04	Date of issuing : July 6 <sup>th</sup> 2012
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## CERTIFICATE OF ANALYSIS

Date: 08.09.2017

<b>Product Name</b>	CLEARLENs BI-SPORE BASE SOLUTION VH26
<b>Product Code</b>	7514852
<b>Batch Number</b>	FMP 17251 / 43366
<b>Production Date</b>	08/09/2017
<b>Expiration Date</b>	EXP 08/09/2019

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 Colourless Liquid		clear colourless liquid
pH (100% 20°C)	JDM001	1.5	2.5	1.6
Specific Gravity (20°C)	JDM004	1.010	1.030	1.020

On behalf of Diversey site Quality Manager	Name :	Pentgists, J. Staan
	Position	Quality Control Inspector

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

COA 7514852	Version : 04	Date of issuing : July 6 <sup>th</sup> 2012
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Ms D Henderson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 15 Sep 2017  
**Date Tested:** 21 Sep 2017  
**Date Test Completed:** 05 Oct 2017  
**Purchase Order:** 29615

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0037966/2  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 15/09/2017  
**Test Article:** Bi-Spore (Activator)  
**Sample Code:** FMP17251 43366  
**Batch Ref:** 583158  
**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 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM04

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

 Mrs C Moore

Date: 06 Oct 2017 12:25:36

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



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

**Date Received:** 15 Sep 2017  
**Date Tested:** 21 Sep 2017  
**Date Test Completed:** 05 Oct 2017  
**Purchase Order:** 29615

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0037966/1  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 15/09/2017  
**Test Article:** Bi-Spore (Base)  
**Sample Code:** FMP17251 43366  
**Batch Ref:** 570742  
**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 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM05

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

 C. Moore, MNSB

Date: 06 Oct 2017 12:25:36

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

# Certificate of Irradiation

Date Issued: 31-Aug-2017

UK33S11947804-3-1

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

## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1106825
Customer Reference Number:	29475
Product Description:	BISP 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:	WO43364, 1 plt

## Irradiation Data

Date and Time of Irradiation:	31-Aug-2017 00:30
Reference Dose Range kGy:	32.7 - 32.8
Calculated Minimum Dose kGy:	27.1
Calculated Maximum Dose kGy:	33.5

Items irradiated under WO43364, will be used in finished product batch FMP17251 43366

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