

Diversey Europe Operations BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date:

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP 13 127 33682
Production Date	05/2013
Expiration Date	05/2014

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		mits	Results
		Lower -	OPPCI	
Appearance	Visual	Clear C	olourless	riceir colourless
		Lic	quid	1120:d
pH (100% 20°C)	JDM001	1.5	2.5	2.0
Specific Gravity (20°C)	JDM004	1.010	1.030	1.017

0.1.1.16.60	Name:	Misur, A. Mostu	Q_
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector	

This document being issued electronically does not bear a signature

COA Bi-Spore Base		Date of issuing: September 27th 2012
	Version: 01	



Diversey Europe Operations BV

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CERTIFICATE OF ANALYSIS

Date: 7.05.13

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP 13 127 33682
Production Date	05/2013
Expiration Date	05/2014

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	Li Lower -	mits Upper	Results
Appearance	Visual		Colourless quid	clear colouriess
pH (100% 20°C)	JDM001	9.0	12.5	12.0
Specific Gravity (20°C)	JDM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	168-75 pm

On behalf of Diversey site Quality Manager	Name :	A. Katua Miscoe
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Activator Version: 01 Date of issuing: October 1st 2012



http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 24-Mar-2013

UK32S11010093-1-1

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

ISO 11137:2006 Sterilisation of Health Care Products ISO 9001:2008 Quality Management System 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

Ord	er Information
Customer Reference Number: Product Description: Validation Reference: Quantity Received: Customer Minimum Specification kGy: Customer Maximum Specification kGy: Customer Unit Lot/Batch Number: Shop Order Number: Synergy Health Sales Part Reference:	P020095 JD-B0TTLES/CAPS/BAGS 25-40kGy 4.0500 8 25.0 40.0 W033679 , 2 PLTS LOT 7 THURS 14.3.13 S11010093-1-1 1002735
Irra	adiation Data
Date and Time of Irradiation: Reference Dose Range kGy: Calculated Minimum Dose kGy: Calculated Maximum Dose kGy:	24-Mar-2013 14:01 33.5 - 34.3 25.5 35.5

Comments: Items irradiated under WO33679 will be used in finished product

FMP13127 33682

09-05-13

Elaugh.



Wickham Laboratories Limited, Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

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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:

09 May 2013

Date Tested:

15 May 2013

Date Test Completed:

29 May 2013

Purchase Order:

20379

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0010202/2

Test Required:

Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Date Received:

09/05/2013

Test Article:

ClearKlens Bio-Spore Base

Sample Code:

FMP13127 33682

Batch Ref:

432030

Qtv Received:

20 x 100mL

4.7 // // // // // // // // // // // // //		
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
Product Standard Data Sheet	FG047/psd	FM05

Comments

Test carried out according to current Pharmacopoeias.

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

MB

Date: 30 May 2013 16:16:59

Mr K.A. Barker, CBiol, MSB

Business Manager - Microbiology

Consignment: 0010202

Certificate of Analysis - OSMM

Print Number: P0010873

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Ms D Henderson

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Test Required:

0010202/2

Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Date Received:

09/05/2013

Test Article:

ClearKlens Bio-Spore Base

Sample Code:

FMP13127 33682

Batch Ref: Qty Received: 432030 20 x 100mL

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
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