synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 06-Sep-2017 **UK33S11952926-1-1**

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:	P029513
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:	W043290, 1 PLTS

Irradiation Data

Date and Time of Irradiation:	05-Sep-2017 23:24
Reference Dose Range kGy:	32.2 - 32.5
Calculated Minimum Dose kGy:	26.7
Calculated Maximum Dose kGy:	33.2

Items irradiated under WO43290, will be used in finished product batch FMP17277 43289

Irradiation Release Authorised By Synergy Health plc

First off

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 04.10.2017

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP 17 277 / 43289
Production Date	04/10/2017
Expiration Date	Exp 04/10/2019

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 Lower - Upper	Results
Appearance	Visual	Clear Colourless Liquid	clear odourless liquid
pH (100% 20°C)	JDM001	1.5 2.5	1.7
Specific Gravity (20°C)	JDM004	1.010 1.030	1.016.

On behalf of Diversey site Quality Manager	Name :	N. Stavan, Olga Ivanna
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

First off

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 04.10.2017

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMF17277 / 43289
Production Date	04/10/2017
Expiration Date	EXP 04/10/2019

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 Lower	Limits Upper	Results
Appearance	Visual	Clear Colourless Liquid		Clear Colourless liquid
pH (100% 20°C)	JDM001	9.0	12.5	11.8
Specific Gravity (20°C)	JDM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	165.375 ppm.

On behalf of Diversey site Quality Manager	Name :	M. Stavan . Olga Kirienne
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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: 13 Oct 2017
Date Tested: 19 Oct 2017
Date Test Completed: 02 Nov 2017
Purchase Order: 29771

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0038535/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 13/10/2017
Test Article: Bi-Spore (Activator)
Sample Code: FMP17277 43289
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.

CBio MNSB Date: 03 Nov 2017 12:50:39

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA

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: 13 Oct 2017
Date Tested: 19 Oct 2017
Date Test Completed: 02 Nov 2017
Purchase Order: 29771

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0038535/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 13/10/2017
Test Article: Bi-Spore (Base)
Sample Code: FMP17277 43289
Batch Ref: 587518
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.

CBio MRSB Date: 03 Nov 2017 12:50:39

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA