

First off



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Tel. +31 (0)30 247 6427  
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## CERTIFICATE OF ANALYSIS

Date: 10/09/2020

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP 20251 50200
Production Date	07/09/2020
Expiration Date	EXP 07/09/2022

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	10.2
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	108

On behalf of Diversey site Quality Manager	Name :	Poutyus, A. Bonys
	Position	Quality Control Inspector

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

Date: 10/09/2020

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP 20251 50200
Production Date	07/09/2020
Expiration Date	EXP 07/09/2022

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	2.5
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	P. Bontjes, A. Bontjes
	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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# STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-13176A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO50191	8	Case
Validation Reference Number: 4725			

Processing Run Start Date: 28-Aug-20 04:07 PM

Processing Run End Date: 28-Aug-20 10:05 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.6
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	35.3

PO Number: 36273

**Gamma Process Run Approval authorized by STERIS**

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

## Processing Location

Synergy Health Sterilisation UK  
Limited, a STERIS Company  
Brunel Close  
Drayton Fields Industrial Estate  
Daventry  
Northants  
NN11 8RB  
Phone: + 44(0) 1327 706 111

Items irradiated under WO50191 will be used in finished batch Fmp20251 50200.

Olga Kirchner

# PHARMACEUTICAL ANALYSIS REPORT

## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Mrs.Olga Kirchner

**Report of Tests on:** Bi-Spore Activator

**Sample Description:** Sample Code: Fmp20251 50200

**Lucideon Sample Number:** UK203751-26386

**Lucideon Report Number:** UK203751-26386/MFEP **Issue Number:** 1

**Date Logged:** 15-Sep-2020 **Order Number:** PO36367

**Date Reported:** 09-Oct-2020 **Date(s) of Test(s):** 24-Sep-2020 to 08-Oct-2020

### Sterility Testing

Membrane Filtration EP


## Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

**End of Test Report**

  
09 OCT 20

Mrs Andrea Saunders

**Business Support Assistant**

Page 1 of 1

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Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.

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# PHARMACEUTICAL ANALYSIS REPORT

**LUCIDEON**

insight creating advantage

## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Mrs.Olga Kirchner

**Report of Tests on:** Bi-Spore Base

**Sample Description:** Sample Code: Fmp20251 50200

**Lucideon Sample Number:** UK203751-26387

**Lucideon Report Number:** UK203751-26387/MFEP **Issue Number:** 1

**Date Logged:** 15-Sep-2020 **Order Number:** PO36367

**Date Reported:** 09-Oct-2020 **Date(s) of Test(s):** 24-Sep-2020 to 08-Oct-2020

### Sterility Testing

Membrane Filtration EP

## Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

**End of Test Report**



Mrs Andrea Saunders

**Business Support Assistant**

Page 1 of 1

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