



Diversey Europe Operations BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 28 October 2022

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP22300	55346	
Production Date	27/10/2022		
Expiration Date	EXP 27/10/2024		

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	11.5
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide		100	180	135

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda    Angelika Partynska
	Position	Quality Control Inspector

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

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

Date: 28 October 2022

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP 22300	55346	
Production Date	27/10/2022		
Expiration Date	EXP 27/10/2024		

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	1.017

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda    Angelika Partynska
	Position	Quality Control Inspector

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## STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-30871A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 Components DV5857	55275	8	Case

Validation Reference Number: 5857

Processing Run Start Date: 03-Sep-2022 11:58 AM

Processing Run End Date: 03-Sep-2022 6:06 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.5
Reference Dose Range (kGy):	26.1 - 35.8	Calculated Max Dose (kGy):	35.9

PO Number: 403324

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

### Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 03-Sep-2022 9:25 PM

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 WO55346 will be used in finished batch Fmp22300 55346.

Document ID: 121396

N/A

Last Revised in Rel 2.0.0.0

Rel Date: 13-Aug-2018

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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 Activator

**Sample Description:** Sample Code: Fmp22300 55346

**Lucideon Sample Number:** UK224527-29558

**Lucideon Report Number:** UK224527-29558/MFEP **Issue Number:** 1

**Date Logged:** 17-Nov-2022 **Order Number:** 403970

**Date Reported:** 08-Dec-2022 **Date(s) of Test(s):** 22-Nov-2022 to 06-Dec-2022

### 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**

NB Boot 08 Dec 22

Mrs Natalie Boot

**Senior Business Support Administrator**

Page 1 of 1

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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: Fmp22300 55346

**Lucideon Sample Number:** UK224527-29559

**Lucideon Report Number:** UK224527-29559/MFEP **Issue Number:** 1

**Date Logged:** 17-Nov-2022 **Order Number:** 403970

**Date Reported:** 08-Dec-2022 **Date(s) of Test(s):** 22-Nov-2022 to 06-Dec-2022

### 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**

Natalie Boot 08 Dec 22

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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