



Diversey Europe Operations BV  
Maarssenbroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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

## CERTIFICATE OF ANALYSIS

Date: 07 July 2023

<b>Product Name</b>	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
<b>Product Code</b>	7515828		
<b>Batch Number</b>	FMP23188	57785	
<b>Production Date</b>	07/07/2023		
<b>Expiration Date</b>	EXP 07/07/2025		

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	1.008
Potential Chlorine Dioxide		100	180	141.75

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Ewelina Nowaczyk
	Position	Quality Control Inspector

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COA Template	Version : 04	Date of issuing : March 11th 2019
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Product Code	7515828		
Batch Number	FMP23188	57785	
Production Date	07/07/2023		
Expiration Date	EXP 07/07/2025		

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	1.9
Specific Gravity (20°C)	DM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Ewelina Nowaczyk
	Position	Quality Control Inspector

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)  
Gamma Process Run ID 2173-38297A

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	57788	8	Case
Validation Reference Number: 5857			

Processing Run Start Date: 24-Jun-2023 4:45 AM  
Processing Run End Date: 24-Jun-2023 10:44 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	29.6
Reference Dose Range (kGy):	26.1 - 35.8	Calculated Max Dose (kGy):	36.3

PO Number: 405585

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 24-Jun-2023 5:44 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 WO57788 will be used in finished batch Fmp23188 57785.

Olga Kirchner

# 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: Fmp23188 57785

**Lucideon Sample Number:** UK232683-20443

**Lucideon Report Number:** UK232683-20443/MFEP **Issue Number:** 1

**Date Logged:** 13-Jul-2023 **Order Number:** 405791

**Date Reported:** 07-Aug-2023 **Date(s) of Test(s):** 19-Jul-2023 to 02-Aug-2023

### 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**

DocuSigned by:

*Natalie Boot*



Signer Name: Natalie Boot  
Signing Reason: I have reviewed this document  
Signing Time: 07 August 2023 | 15:45 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator**

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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: Fmp23188 57785

**Lucideon Sample Number:** UK232683-20444

**Lucideon Report Number:** UK232683-20444/MFEP **Issue Number:** 1

**Date Logged:** 13-Jul-2023 **Order Number:** 405791

**Date Reported:** 07-Aug-2023 **Date(s) of Test(s):** 19-Jul-2023 to 02-Aug-2023

### 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**

DocuSigned by:

*Natalie Boot*



Signer Name: Natalie Boot  
Signing Reason: I have reviewed this document  
Signing Time: 07 August 2023 | 15:45 BST

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Mrs Natalie Boot

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