



Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 05 July 2022

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7515828		
Batch Number	FMP22186	54510	
Production Date	05/07/2022		
Expiration Date	EXP 05/07/2024		

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	12.0
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide		100	180	121.5

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Angelika Partynska
	Position	Quality Control Inspector

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

Date: 05 July 2022

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off		
Product Code	7515828		
Batch Number	FMP22186	54510	
Production Date	05/07/2022		
Expiration Date	EXP 05/07/2024		

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	1.9
Specific Gravity (20°C)	DM004	1.010	1.030	1.015

On behalf of Diversey site Quality Manger	Name:	Justyna Staron 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 2173-27637A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 Components DV5857	54515	8	Case
Validation Reference Number: 5857			

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	30.9
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Reference Dose Range (kGy):	26.1 - 35.8	Calculated Max Dose (kGy):	37.7
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PO Number: 402391

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

Signature Manifest

Reviewed and E-Signed By: **Nelia Dias (Quality Engineer)**

Date/Time E-Signed: 19-Apr-2022 9:46 AM

Document Content Revision: 1

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 WO54515 will be used in finished batch Fmp22186 54510.

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: Fmp22186 54510

Lucideon Sample Number: UK222895-18561

Lucideon Report Number: UK222895-18561/MFEP **Issue Number:** 1

Date Logged: 18-Jul-2022 **Order Number:** 403033

Date Reported: 09-Aug-2022 **Date(s) of Test(s):** 20-Jul-2022 to 03-Aug-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 09-Aug-22

Mrs Natalie Boot

Senior Business Support Administrator

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



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: Fmp22186 54510

Lucideon Sample Number: UK222895-18562

Lucideon Report Number: UK222895-18562/MFEP **Issue Number:** 1

Date Logged: 18-Jul-2022 **Order Number:** 403033

Date Reported: 09-Aug-2022 **Date(s) of Test(s):** 20-Jul-2022 to 03-Aug-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 09-Aug-22

Mrs Natalie Boot

Senior Business Support Administrator

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