



Diversey Europe BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 27 April 2022

Product Name	CLEARLENs BI-SPORE BASE SOLUTION VH26- first off
Product Code	7514852
Batch Number	FMP22117 53994
Production Date	27/04/2022
Expiration Date	EXP 27/04/2024

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	1.8
Specific Gravity (20°C)	DM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	Justyna Staron, A.Partynska
	Position	Quality Control Inspector

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

Date: 27 April 2022

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off		
Product Code	7514852		
Batch Number	FMP22117	53994	
Production Date	27/04/2022		
Expiration Date	EXP 27/04/2024		

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	12.5
Specific Gravity (20°C)	DM004	1.004	1.020	1.007
Potential Chlorine Dioxide (ppm)		100	180	135

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 2173-27517A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 Components DV5857	54181	8	Case
Validation Reference Number: 5857			

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):	36.6

PO Number: 402044

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 16-Apr-2022 12:07 AM



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 WO53994 will be used in finished batch FMP22117 53994.

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:FMP22117 53994

Lucideon Sample Number: UK221805-11475

Lucideon Report Number: UK221805-11475/MFEP **Issue Number:** 1

Date Logged: 03-May-2022 **Order Number:** 402487

Date Reported: 26-May-2022 **Date(s) of Test(s):** 12-May-2022 to 26-May-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 26 May 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

LUCIDEON

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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:FMP22117 53994

Lucideon Sample Number: UK221805-11476

Lucideon Report Number: UK221805-11476/MFEP **Issue Number:** 1

Date Logged: 03-May-2022 **Order Number:** 402487

Date Reported: 26-May-2022 **Date(s) of Test(s):** 12-May-2022 to 26-May-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

N. Boot 26 May 22

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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