



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 19/05/2022

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 FIRST OFF
Product Code	7514852
Batch Number	FMP22139 55092
Production Date	19/05/2022
Expiration Date	EXP 19/05/2024

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	12.3
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	148.5

On behalf of Diversey site Quality Manager	Name :	U.Haraburda J.Staron
	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: 19/05/2022

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 FIRST OFF
Product Code	7514852
Batch Number	FMP22139 55092
Production Date	19/05/2022
Expiration Date	EXP 19/05/2024

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	1.014

On behalf of Diversey site Quality Manager	Name :	U.Haraburda J.Staron
	Position	Quality Control Inspector

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COA Template

Version : 02

Date of Issuing : November 24th 2017

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-28064A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 Components DV5857	55091	3	Case
Validation Reference Number: 5857			

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	30.9
Reference Dose Range (kGy):	26.1 - 35.8	Calculated Max Dose (kGy):	36.2

PO Number: 402495

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

Signature Manifest

Reviewed and E-Signed By: **Tamas Szatmari (Quality Engineer)**

Date/Time E-Signed: 09-May-2022 12:46 PM

Document Content Revision: 2

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 WO55091 will be used in finished batch FMP22139 55092.

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: Fmp22139 55092

Lucideon Sample Number: UK222247-14294

Lucideon Report Number: UK222247-14294/MFEP **Issue Number:** 1

Date Logged: 27-May-2022 **Order Number:** 402671

Date Reported: 16-Jun-2022 **Date(s) of Test(s):** 01-Jun-2022 to 15-Jun-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 16-Jun-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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Unit 8
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White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Bi-Spore Base

Sample Description: Sample Code: Fmp22139 55092

Lucideon Sample Number: UK222247-14295

Lucideon Report Number: UK222247-14295/MFEP **Issue Number:** 1

Date Logged: 27-May-2022 **Order Number:** 402671

Date Reported: 16-Jun-2022 **Date(s) of Test(s):** 01-Jun-2022 to 15-Jun-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 16-Jun-22

Mrs Natalie Boot

Senior Business Support Administrator

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