Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 26 July 2022

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off
Product Code	7514852
Batch Number	FMP22207 54772
Production Date	26/07/2022
Expiration Date	EXP 26/07/2024

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 Lower	- Upper	Results
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
pH (neat solution)	DM001	9.0	12.5	11.3
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide		100	180	145.125

On behalf of Diversey site Quality Manger	Name:	Justyna Staron 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*

Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 26 July 2022

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off
Product Code	7514852
Batch Number	FMP22207 54772
Production Date	26/07/2022
Expiration Date	EXP 26/07/2024

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 Lower - Upper**		**Results**
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	1.016

On behalf of Diversey site Quality Manger	Name:	Justyna Staron 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*

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: Fmp22207 54772		
Lucideon Sample Number:	UK223121-20018		
Lucideon Report Number:	UK223121-20018/MFEP	**Issue Number:**	1
Date Logged:	03-Aug-2022	**Order Number:**	403140
Date Reported:	19-Aug-2022	**Date(s) of Test(s):**	05-Aug-2022 **to** 19-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

NCBoot 19-Aug-22

Mrs Natalie Boot
Senior Business Support Administrator

Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com

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: Fmp22207 54772		
Lucideon Sample Number:	UK223121-20017		
Lucideon Report Number:	UK223121-20017/MFEP	**Issue Number:**	1
Date Logged:	03-Aug-2022	**Order Number:**	403140
Date Reported:	19-Aug-2022	**Date(s) of Test(s):**	05-Aug-2022 **to** 19-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

NcBoot 19-Aug-22

Mrs Natalie Boot
Senior Business Support Administrator

Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com

STERIS: Gamma Certificate Of Processing

Prepared for: **FLEXIBLE MEDICAL PACKAGING LTD (8245)**

Gamma Process Run ID **2173-28924A**

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	**54832**	**15**	**Case**

Validation Reference Number: 5857

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**30.3**
Reference Dose Range (kGy):	**26.1 - 35.8**	**Calculated Max Dose (kGy):**	**35.9**

PO Number: 402719

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: 15-Jun-2022 8:36 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 WO54832 will be used in finished batch Fmp22207 54772.

Olga Kirchner