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	7515828
Batch Number	FMP22199 54445
Production Date	18/07/2022
Expiration Date	EXP 18/07/2024

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	11.5
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide		100	180	138.375

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda 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*

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CERTIFICATE OF ANALYSIS

Date: 26 July 2022

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off
Product Code	7515828
Batch Number	FMP22199 54445
Production Date	18/07/2022
Expiration Date	EXP 18/07/2024

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	2.0
Specific Gravity (20°C)	DM004	1.010	1.030	1.015

On behalf of Diversey site Quality Manger	Name:	Urszula Haraburda Angelika Partynska
	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 **2173-28061A**

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	**54506**	**8**	**Case**

Validation Reference Number: 5857

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**30.4**
Reference Dose Range (kGy):	**26.1 - 35.8**	**Calculated Max Dose (kGy):**	**36.7**

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 12:48 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 WO54506 will be used in finished batch Fmp22199 54445.

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: Fmp22199 54445		
Lucideon Sample Number:	UK223076-19812		
Lucideon Report Number:	UK223076-19812/MFEP	**Issue Number:**	1
Date Logged:	29-Jul-2022	**Order Number:**	403116
Date Reported:	19-Aug-2022	**Date(s) of Test(s):**	04-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

Refer to Deviation (DEV) 6557.

End of Test Report

NBoot 19-Aug-22

Mrs Natalie Boot
Senior Business Support Administrator

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.

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Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Bi-Spore Base

Sample Description: Sample Code: Fmp22199 54445

Lucideon Sample Number: UK223076-19813

Lucideon Report Number: UK223076-19813/MFEP **Issue Number:** 1

Date Logged: 29-Jul-2022 **Order Number:** 403116

Date Reported: 19-Aug-2022 **Date(s) of Test(s):** 04-Aug-2022 **to** 19-Aug-2022

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Membrane Filtration EP

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