Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 27 July 2023

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 first off
Product Code	101105911
Batch Number	FMP23208 57651
Production Date	27/07/2023
Expiration Date	EXP 27/07/2025

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:	Justyna Staron Natlia Traichel
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	*Version : 04*	*Date of issuing : March 11th 2019*

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CERTIFICATE OF ANALYSIS

Date: 27 July 2023

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26 first off
Product Code	101105911
Batch Number	FMP23208 57651
Production Date	27/07/2023
Expiration Date	EXP 27/07/2025

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	1.8
Specific Gravity (20°C)	DM004	1.010	1.030	1.020

On behalf of Diversey site Quality Manger	Name:	Justyna Staron Natlia Traichel
	Position	Quality Control Inspector

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COA Template	*Version : 04*	*Date of issuing : March 11th 2019*

STERIS: Gamma Certificate Of Processing

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

Gamma Process Run ID **2173-38298A**

Product Code	Lot Number	Quantity	UOM
BI-SP B3 Components DV5857	**57669**	**8**	**Case**

Validation Reference Number: 5857

Processing Run Start Date: 24-Jun-2023 4:56 AM

Processing Run End Date: 24-Jun-2023 10:54 AM

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**30.6**
Reference Dose Range (kGy):	**26.1 - 35.8**	**Calculated Max Dose (kGy):**	**36.1**

PO Number: 405585

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 24-Jun-2023 5:47 PM

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 WO57669 will be used in finished batch Fmp23208 57651.

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: Fmp23208 57651

Lucideon Sample Number: UK232996-22574

Lucideon Report Number: UK232996-22574/MFEP **Issue Number:** 1

Date Logged: 04-Aug-2023 **Order Number:** 405978

Date Reported: 01-Sep-2023 **Date(s) of Test(s):** 18-Aug-2023 **to** 01-Sep-2023

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

DocuSigned by:
Natalie Boot
Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 01 September 2023 | 15:22 BST
90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot
Senior Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

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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: Fmp23208 57651

Lucideon Sample Number: UK232996-22575

Lucideon Report Number: UK232996-22575/MFEP **Issue Number:** 1

Date Logged: 04-Aug-2023 **Order Number:** 405978

Date Reported: 01-Sep-2023 **Date(s) of Test(s):** 18-Aug-2023 **to** 01-Sep-2023

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

DocuSigned by:
Natalie Boot
Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 01 September 2023 | 15:22 BST
90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot
Senior Business Support Administrator

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Queens Road
Stoke-on-Trent, Staffordshire ST4 7LQ
Natalie.Boot@uk.lucideon.com
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