



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 18/11/2020

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP 20323 50591
Production Date	18/11/2020
Expiration Date	Exp 18/11/2022

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	11.4
Specific Gravity (20°C)	DM004	1.004	1.020	1.009
Potential Chlorine Dioxide (ppm)		100	180	145.125 ppm

On behalf of Diversey site Quality Manager	Name :	A. Bony, Karabudwa
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 th 2017
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FIRST OFF



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CERTIFICATE OF ANALYSIS

Date: 18/11/2020

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP 20323 50591
Production Date	18/11/2020
Expiration Date	Exp 18/11/2022

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	1.016

On behalf of Diversey site Quality Manager	Name :	Harabirida, A. Bouys
	Position	Quality Control Inspector

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-14375A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO50590	8	Case
Validation Reference Number: 4725			

Processing Run Start Date: 16-Oct-20 02:50 AM

Processing Run End Date: 16-Oct-20 08:37 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	26.7
Reference Dose Range (kGy):	30.2 - 39.2	Calculated Max Dose (kGy):	34.0

PO Number: 36617

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: 2020-10-19 10:53 AM

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 WO50590 will be used in finished batch Fmp20323 50591.

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: Fmp20323 50591

Lucideon Sample Number: UK204796-33932

Lucideon Report Number: UK204796-33932/MFEP **Issue Number:** 1

Date Logged: 23-Nov-2020 **Order Number:** PO36874

Date Reported: 18-Dec-2020 **Date(s) of Test(s):** 30-Nov-2020 to 18-Dec-2020

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 18-Dec-20

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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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: Fmp20323 50591

Lucideon Sample Number: UK204796-33933

Lucideon Report Number: UK204796-33933/MFEP **Issue Number:** 1

Date Logged: 23-Nov-2020 **Order Number:** PO36874

Date Reported: 18-Dec-2020 **Date(s) of Test(s):** 30-Nov-2020 to 18-Dec-2020

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Membrane Filtration EP

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No Boot 18-Dec-20

Mrs Natalie Boot

Senior Business Support Assistant

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