

First off



Diversey Europe Operations BV
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The Netherlands

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www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 18/08/2020

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP 20226 50110
Production Date	13/08/2020
Expiration Date	EXP 13/08/2022

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	11.1
Specific Gravity (20°C)	DM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	141.75 ppm

On behalf of Diversey site Quality Manager	Name :	Pattyuslo Jstawan
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of issuing : November 24 th 2017
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Date: 18/08/2020

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FHP 20226 50110
Production Date	13/08/2020
Expiration Date	EXP 13/08/2022

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	1.6
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	Patty USB J. Staver
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of Issuing : November 24 th 2017
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-12100A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO50109	8	Case

Validation Reference Number: 4725

Processing Run Start Date: 22-Jul-20 10:17 AM

Processing Run End Date: 22-Jul-20 04:04 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	27.2
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	34.3

PO Number: 35939

Gamma Process Run Approval authorized by STERIS

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 WO50109 will be used in finished batch FMP20226 50110.

Olga Kirchner

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs Caaren Beales

Report of Tests on: Bi Spore Activator

Sample Description: Sample Code: Fmp20226 50110

Lucideon Sample Number: UK203428-24286

Lucideon Report Number: UK203428-24286/MFEP **Issue Number:** 1

Date Logged: 24-Aug-2020 **Order Number:** PO36237

Date Reported: 15-Oct-2020 **Date(s) of Test(s):** 18-Sep-2020 to 02-Oct-2020

Sterility Testing

Membrane Filtration EP

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

End of Test Report

Natalie Boot 15-Oct-20

Mrs Natalie Boot

Senior Business Support Assistant

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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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs Caaren Beales

Report of Tests on: Bi Spore Base

Sample Description: Sample Code: Fmp20226 50110

Lucideon Sample Number: UK203428-24287

Lucideon Report Number: UK203428-24287/MFEP **Issue Number:** 1

Date Logged: 24-Aug-2020 **Order Number:** PO36237

Date Reported: 15-Oct-2020 **Date(s) of Test(s):** 18-Sep-2020 to 02-Oct-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 Boot 15-001-20

Mrs Natalie Boot

Senior Business Support Assistant

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