



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 06/05/2020

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP 20127, 49523
Production Date	06/05/2020
Expiration Date	Exp 06/05/2022

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	12.0
Specific Gravity (20°C)	DM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	128.25 ppm

On behalf of Diversey site Quality Manager	Name :	J. Stuurman Quality Control Inspector
	Position	

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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: 06/05/2020

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7574852
Batch Number	FMP 20127, 49523
Production Date	06/05/2020
Expiration Date	EXP 06/05/2022

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 :	J. Staan Poutjes
	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: 2173-10057A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO49522	8	Case

Validation Reference Number: 4725

Processing Run Start Date: 26-Apr-20 08:11 AM

Processing Run End Date: 26-Apr-20 01:43 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	26.8
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	33.7

PO Number: PO35283

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 WO49522 will be used in finished batch Fmp20127 49523.

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: Fmp20127 49523

Lucideon Sample Number: UK202136-15910

Lucideon Report Number: UK202136-15910/MFEP **Issue Number:** 1

Date Logged: 21-May-2020 **Order Number:** PO 35516

Date Reported: 11-Jun-2020 **Date(s) of Test(s):** 24-May-2020 to 11-Jun-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 11-Jun-20

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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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: Fmp20127 49523

Lucideon Sample Number: UK202136-15911

Lucideon Report Number: UK202136-15911/MFEP **Issue Number:** 1

Date Logged: 21-May-2020 **Order Number:** PO 35516

Date Reported: 11-Jun-2020 **Date(s) of Test(s):** 24-May-2020 to 11-Jun-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 11-JUN-20

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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