



Diversey Europe Operations BV Mearssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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### CERTIFICATE OF ANALYSIS

Date: 19/06/2020

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP20169, 49667
Production Date	17106/2020
Expiration Date	EXP 17/06/2022

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	<ul> <li>Upper</li> </ul>	
Appearance	Visual	Clear Colourless Liquid		clear colaines
pH (neat solution)	DM001	9.0	12.5	11.6
Specific Gravity (20°C)	DM004	1.004	1.020	1. 005
Potential Chlorine Dioxide (ppm)		100	180	138.375 ppm

	Name :	Stavar Partyrolo
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector

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



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## **CERTIFICATE OF ANALYSIS**

Date: 19/06/2020

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26		
Product Code			
Batch Number			
Production Date	MF 10612020		
Expiration Date	Exp. 17 10012022		

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 Clear Colourless Liquid		Results
Appearance	Visual			clean Colounia
pH (neat solution)	DM001	1.5	2.5	1.3
Specific Gravity (20°C)	DM004	1.010	1.030	1,016

On behalf of Diversey site Quality Manager	Name:	Partyuster, Marabude
	Position	Quality Control Inspector

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

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-10785A

Product CodeLot NumberQuantityUOMBI-SP B3 COMPONENTS DV4725WO496668 Case

Validation Reference Number: 4725

Processing Run Start Date: 24-May-20 03:09 PM

Processing Run End Date: 24-May-20 09:02 PM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 25.4 Reference Dose Range (kGy): 30.2-39.2 Calculated Max Dose (kGy): 33.4

PO Number: 35521

### 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 WO49667 woll be used in finished batch Fmp20169 49667.

Olga Kirchner

Rel Date: 08/13/2018

Document ID: 51396

Last Revised in Rel 2.0.0.0

### PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Bi-Spore Activator

Sample Description:

Sample Code: Fmp20169 49667

Lucideon Sample Number: UK202591-18863

Lucideon Report Number: UK202591-18863/MFEP

Issue Number:

Date Logged:

24-Jun-2020

Order Number:

PO 35764

Date Reported:

15-Jul-2020

Date(s) of Test(s):

02-Jul-2020 to 15-Jul-2020

Sterility Testing

Membrane Filtration EP

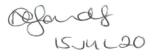
Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

**End of Test Report** 



# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO: Mrs.Olga Kirchner

Report of Tests on:

Bi-Spore Base

Sample Description:

Sample Code: Fmp20169 49667

Lucideon Sample Number: UK202591-18864

Lucideon Report Number: UK202591-18864/MFEP

Issue Number:

1

Date Logged:

24-Jun-2020

Order Number:

PO 35764

Date Reported:

15-Jul-2020

Date(s) of Test(s):

02-Jul-2020

to 15-Jul-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** 

Mrs Andrea Saunders

**Business Support Assistant** 

Lucideon Limited

Stoke-on-Trent