Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
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FIRST OFF

CERTIFICATE OF ANALYSIS

Date: 23/11/2020

Product Name	**CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26**
Product Code	7514852
Batch Number	FMP 20325 50347
Production Date	20/11/2020
Expiration Date	Exp 20/11/2022

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 Lower	Limits Upper	Results
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
pH (neat solution)	DM001	9.0	12.5	11.3
Specific Gravity (20°C)	DM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	148.5

On behalf of Diversey site Quality Manager	Name :	Havaburda, A. Bonys
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	*Version : 02*	*Date of Issuing : November 24th 2017*

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FIRST OFF

CERTIFICATE OF ANALYSIS

Date: 20/11/2020

Product Name	**CLEARKLENS BI-SPORE BASE SOLUTION VH26**
Product Code	7514852
Batch Number	FMP 20325 50347
Production Date	20/11/2020
Expiration Date	Exp 20/11/2022

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 Lower	Limits 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	1.016

On behalf of Diversey site Quality Manager	Name :	A. Borys, Kawabunda
	Position	Quality Control Inspector

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

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-14047A

Product Code	Lot Number	Quantity	UOM
BI-SP B3 COMPONENTS DV4725	WO50346	8	Case

Validation Reference Number: 4725

Processing Run Start Date: 08-Oct-20 09:42 AM

Processing Run End Date: 08-Oct-20 03:53 PM

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**28.0**
Reference Dose Range (kGy):	**30.2 - 39.2**	**Calculated Max Dose (kGy):**	**35.0**

PO Number: 36493

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 WO50346 will be used in finished batch Fmp20325 50347

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: Fmp20325 50347		
Lucideon Sample Number:	UK204872-34044		
Lucideon Report Number:	UK204872-34044/MFEP	**Issue Number:**	1
Date Logged:	27-Nov-2020	**Order Number:**	PO 36896
Date Reported:	18-Dec-2020	**Date(s) of Test(s):**	02-Dec-2020 **to** 16-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

NcBoot 18-Dec-20

Mrs Natalie Boot
Senior Business Support Assistant

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.

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PHARMACEUTICAL ANALYSIS REPORT

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White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on:	Bi - Spore Base		
Sample Description:	Sample Code: FMP20325 50347		
Lucideon Sample Number:	UK204872-34045		
Lucideon Report Number:	UK204872-34045/MFEP	**Issue Number:**	1
Date Logged:	27-Nov-2020	**Order Number:**	PO 36896
Date Reported:	18-Dec-2020	**Date(s) of Test(s):**	02-Dec-2020 **to** 16-Dec-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

NcBoot 18-Dec-20

Mrs Natalie Boot
Senior Business Support Assistant

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