FIRST OFF

Diversey Europe BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 26/11/2019

Product Name	**CLEARKLENS BI-SPORE BASE SOLUTION VH26**
Product Code	75/4852
Batch Number	FHP19322 . 48490
Production Date	18/11/2019
Expiration Date	EXP 18/11/2021

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	2.1
Specific Gravity (20°C)	DM004	1.010	1.030	1.020

On behalf of Diversey site Quality Manager	Name :	Navaneetha J. Stanon
	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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CERTIFICATE OF ANALYSIS

Date: 26/11/2019

Product Name	**CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26**
Product Code	7514852
Batch Number	FMP19322 . 48490
Production Date	18/11/2019
Expiration Date	EXP 18/11/2021

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	11.7
Specific Gravity (20°C)	DM004	1.004	1.020	1.012
Potential Chlorine Dioxide (ppm)		100	180	128.25

On behalf of Diversey site Quality Manager	Name :	Nawabuda . J. Stavon
	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: 2173-5506A

Product Code	Lot Number	Quantity	UOM
BI-SP B3 COMPONENTS DV4725	WO48489	8	Case

Validation Reference Number: 4725

Processing Run Start Date: 09-Oct-19 01:29 PM

Processing Run End Date: 09-Oct-19 07:50 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**

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 WO48489 wiil be used in finished batch Fmp19322 48490.

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: Fmp19322 48490		
Lucideon Sample Number:	(196493)-49582		
Lucideon Report Number:	(196493)-49582/MFEP	**Issue Number:**	1
Date Logged:	29-Nov-2019	**Order Number:**	PO 34383
Date Reported:	18-Dec-2019	**Date(s) of Test(s):**	01-Dec-2019 **to** 15-Dec-2019

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

NBoot 18-Dec-19

Mrs Natalie Boot
Senior Business Support Assistant

Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
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PHARMACEUTICAL ANALYSIS REPORT

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Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on:	Bi-Spore Base		
Sample Description:	Sample Code: Fmp 19322 48490		
Lucideon Sample Number:	(196493)-49583		
Lucideon Report Number:	(196493)-49583/MFEP	**Issue Number:**	1
Date Logged:	29-Nov-2019	**Order Number:**	PO 34383
Date Reported:	18-Dec-2019	**Date(s) of Test(s):**	01-Dec-2019 **to** 15-Dec-2019

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-19

Mrs Natalie Boot
Senior Business Support Assistant

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