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: 08.11.2019

Product Name	**CLEARKLENS BI-SPORE BASE SOLUTION VH26**
Product Code	7515828
Batch Number	FMP 19312 . 48488
Production Date	08.11.2019
Expiration Date	EXP 08/11/2021

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	1.7
Specific Gravity (20°C)	DM004	1.010	1.030	1.020

On behalf of Diversey site Quality Manager	Name :	Stavan Partyush
	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: 08.11.2019

Product Name	**CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26**
Product Code	7515828
Batch Number	FMP 19312 . 48488
Production Date	08.11.2019
Expiration Date	EXP 08/11/2021

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	1.008
Potential Chlorine Dioxide (ppm)		100	180	135 ppm

On behalf of Diversey site Quality Manager	Name :	A. Bonga . J. Stawa
	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: 2173-5507A

Product Code	Lot Number	Quantity	UOM
BI-SP B3 COMPONENTS DV4725	WO48487	8	Case

Validation Reference Number: 4725

Processing Run Start Date: 09-Oct-19 01:36 PM

Processing Run End Date: 09-Oct-19 08:02 PM

Specified Dose Range (kGy):	**25.0 - 40.0**	**Calculated Min Dose (kGy):**	**26.6**
Reference Dose Range (kGy):	**30.2- 39.2**	**Calculated Max Dose (kGy):**	**33.6**

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 WO48487 will be used in finished batch Fmp19312 48488.

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: Fmp19312 48488

Lucideon Sample Number: (196384)-48694

Lucideon Report Number: (196384)-48694/MFEP **Issue Number:** 1

Date Logged: 22-Nov-2019 **Order Number:** PO34324

Date Reported: 13-Dec-2019 **Date(s) of Test(s):** 26-Nov-2019 **to** 10-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 13-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: Fmp19312 48488		
Lucideon Sample Number:	(196384)-48695		
Lucideon Report Number:	(196384)-48695/MFEP	**Issue Number:**	1
Date Logged:	22-Nov-2019	**Order Number:**	PO34324
Date Reported:	13-Dec-2019	**Date(s) of Test(s):**	26-Nov-2019 **to** 10-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 13-Dec-19
Mrs Natalie Boot
Senior Business Support Assistant

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