

FIRST OFF



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 10.02.2020

| | |
|-----------------|---|
| Product Name | CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 |
| Product Code | 7514852 |
| Batch Number | FNP20041, 48709 |
| Production Date | 10.02.2020 |
| Expiration Date | EXP 10/02/2022 |

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 | 11.6 |
| Specific Gravity (20°C) | DM004 | 1.004 | 1.020 | 1.008 |
| Potential Chlorine Dioxide (ppm) | | 100 | 180 | 124.875 ppm |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | A. Bony Pabys |
| | Position | Quality Control Inspector |

This document being Issued electronically does not bear a signature

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

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CERTIFICATE OF ANALYSIS

Date: 10.02.2020

| | |
|-----------------|--|
| Product Name | CLEARKLENS BI-SPORE BASE SOLUTION VH26 |
| Product Code | 7514852 |
| Batch Number | FMP20041, 48709 |
| Production Date | 10.02.2020 |
| Expiration Date | EXP 10/02/2022 |

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 | 2.0 |
| Specific Gravity (20°C) | DM004 | 1.010 | 1.030 | 1.016 |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | J. Staan, A. Bony |
| | 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: 2173-7355A

| <u>Product Code</u> | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|----------------------------|-------------------|-----------------|------------|
| BI-SP B3 COMPONENTS DV4725 | WO48710 | 8 | Case |

Validation Reference Number: 4725

Processing Run Start Date: 10-Jan-20 04:53 PM

Processing Run End Date: 11-Jan-20 01:29 AM

| | | | |
|-----------------------------|-------------|----------------------------|------|
| 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: PO34552 MOC APPLIES TO THIS ORDER

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By: **Bhavya Ramisetty (Quality Engineer)**

Date/Time E-Signed: 2020-01-14 09:26 AM

Document Content Revision: 1

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 WO48710 will be used in finished batch Fmp20041 48709

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: Fmp20041 48709

Lucideon Sample Number: UK20855-6384

Lucideon Report Number: UK20855-6384/MFEP

Issue Number: 1

Date Logged: 20-Feb-2020

Order Number: PO34800

Date Reported: 12-Mar-2020

Date(s) of Test(s): 23-Feb-2020 to 08-Mar-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

NOROOT 12-Mar-20

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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

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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 Base

Sample Description: Sample Code: Fmp20041 48709

Lucideon Sample Number: UK20855-6385

Lucideon Report Number: UK20855-6385/MFEP

Issue Number: 1

Date Logged: 20-Feb-2020

Order Number: PO34800

Date Reported: 12-Mar-2020

Date(s) of Test(s): 23-Feb-2020 to 08-Mar-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

NOBOK 12-MAR-20

Mrs Natalie Boot

Senior Business Support Assistant

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