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: 09/09/2020

| | |
|---|---|
| **Product Name** | **CLEARKLENS BI-SPORE BASE SOLUTION VH26** |
| **Product Code** | 7514852 |
| **Batch Number** | FMP20253 50201 |
| **Production Date** | 09/09/2020 |
| **Expiration Date** | EXP 09/09/2022 |

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 | 2.5 |
| Specific Gravity (20°C) | DM004 | 1.010 | 1.030 | 1.016 |

| | | |
|---|---|---|
| On behalf of Diversey site Quality Manager | Name : | Navahuda Pantyusha |
| | Position | Quality Control Inspector |

*This document being issued electronically does not bear a signature*

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

FIRST OFF

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The Netherlands

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# CERTIFICATE OF ANALYSIS

Date: 09/09/2020

| | |
|---|---|
| **Product Name** | **CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26** |
| **Product Code** | 7514852 |
| **Batch Number** | FHP20253 , 50201 |
| **Production Date** | 09/09/2020 |
| **Expiration Date** | EXP 09/09/2022 |

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 | 10.2 |
| Specific Gravity (20°C) | DM004 | 1.004 | 1.020 | 1.005 |
| Potential Chlorine Dioxide (ppm) | | 100 | 180 | 108 ppm |

| | | |
|---|---|---|
| On behalf of Diversey site Quality Manager | Name : | Nawalwada Ishaan |
| | Position | Quality Control Inspector |

*This document being issued electronically does not bear a signature*

| | | |
|---|---|---|
| *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: 2173-13176A**

| Product Code | Lot Number | Quantity | UOM |
|---|---|---|---|
| BI-SP B3 COMPONENTS DV4725 | WO50191 | 8 | Case |

**Validation Reference Number:** 4725

**Processing Run Start Date: 28-Aug-20 04:07 PM**

**Processing Run End Date: 28-Aug-20 10:05 PM**

| | | | |
|---|---|---|---|
| **Specified Dose Range (kGy):** | **25.0 - 40.0** | **Calculated Min Dose (kGy):** | **28.6** |
| **Reference Dose Range (kGy):** | **30.2- 39.2** | **Calculated Max Dose (kGy):** | **35.3** |

PO Number: 36273

**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 WO50192 will be used in finished batch FMP20253 50201.

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: Fmp20253 50201 | | |
| **Lucideon Sample Number:** | UK203810-26785 | | |
| **Lucideon Report Number:** | UK203810-26785/MFEP | **Issue Number:** | 1 |
| **Date Logged:** | 18-Sep-2020 | **Order Number:** | PO36404 |
| **Date Reported:** | 12-Oct-2020 | **Date(s) of Test(s):** | 25-Sep-2020 **to** 09-Oct-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**

NCBook 12-Oct-20

Mrs Natalie Boot
**Senior Business Support Assistant**





Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

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# PHARMACEUTICAL ANALYSIS REPORT

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**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: Fmp20253 50201 | | |
| **Lucideon Sample Number:** | UK203810-26786 | | |
| **Lucideon Report Number:** | UK203810-26786/MFEP | **Issue Number:** | 1 |
| **Date Logged:** | 18-Sep-2020 | **Order Number:** | PO36404 |
| **Date Reported:** | 12-Oct-2020 | **Date(s) of Test(s):** | 25-Sep-2020 **to** 09-Oct-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 12-Oct-20

Mrs Natalie Boot
**Senior Business Support Assistant**





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