Diversey Europe Operations BV
Maarssenbroeksedijk 2
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The Netherlands

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

# CERTIFICATE OF ANALYSIS

Date: 16.01.2020

| | |
|---|---|
| **Product Name** | **CLEARKLENS TEGO 2000SS VH25S** |
| **Product Code** | 7516427 |
| **Batch Number** | FMP19338 48708 |
| **Production Date** | 04/12/2019 |
| **Expiration Date** | EXP 04/06/2021 |

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 - Upper | | Results |
|---|---|---|---|---|
| Appearance | Visual | Clear Slightly Yellow Liquid | | Clear Slightly Yellow Liquid |
| pH (neat solution) | DM001 | 6.2 | 8.2 | 7.4 |
| Specific Gravity (20°C) | DM004 | 0.990 | 1.010 | 1.000 |

| | | |
|---|---|---|
| On behalf of Diversey site Quality Manager | Name : | M. Navaburda Partyka |
| | 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: 2173-6951A**

| Product Code | Lot Number | Quantity | UOM |
|---|---|---|---|
| **TEGO 2000SS BLK1 DV4767** | **FMP19338 48708** | **59** | **Case** |
| **Validation Reference Number:** 4767 | | | |
| **TEGO 2000SS BLK1 DV4767** | **FMP19338 48708 Inc 4 Samples** | **4** | **Case** |
| **Validation Reference Number:** 4767 | | | |

**Processing Run Start Date: 23-Dec-19 04:22 AM**

**Processing Run End Date: 23-Dec-19 11:56 AM**

| | | | |
|---|---|---|---|
| **Specified Dose Range (kGy):** | **25.0 - 45.0** | **Calculated Min Dose (kGy):** | **27.8** |
| **Reference Dose Range (kGy):** | **31.5- 39.7** | **Calculated Max Dose (kGy):** | **40.4** |

PO Number: 34449

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: 2019-12-24 10:08 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**

# PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON
insight creating advantage

**Flexible Medical Packaging**
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Miss Caroline Pascoe

| | | | |
|---|---|---|---|
| **Report of Tests on:** | Tego 2000SS | | |
| **Sample Description:** | Sample Code: Fmp19338 48708 | | |
| **Lucideon Sample Number:** | UK20249-2278 | | |
| **Lucideon Report Number:** | UK20249-2278/MFEP | **Issue Number:** | 1 |
| **Date Logged:** | 17-Jan-2020 | **Order Number:** | PO34594 |
| **Date Reported:** | 06-Feb-2020 | **Date(s) of Test(s):** | 21-Jan-2020 **to** 04-Feb-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 06-Feb-20.

Mrs Natalie Boot
**Senior Business Support Assistant**





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