Diversey Europe BV
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# CERTIFICATE OF ANALYSIS

Date issue: 23/01/2023

| | |
|---|---|
| **Product Name** | DI Tego 2000 S 50x0.05L |
| **Product Code** | 101107171 |
| **Batch Number** | FMP23003 55625 |
| **Production date** | 03/01/2023 |
| **Expiration Date** | EXP 03/01/2026 |

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 | Specification | Unit | Conformity |
|---|---|---|---|---|
| Appearance | Visual | Colorless Liquid Clear | N/A | Colorless Liquid Clear |
| Specific Gravity (20ºC) | DM 004 | 0.993 – 1.003 | g/cm$^3$ | 1.000 |
| pH (neat Solution | DM 001 | 7.5 – 8.5 | N/A | 8.3 |

Control of the Sterility of the product:

| Test | Test Method | Specification | Conformity | Reference number |
|---|---|---|---|---|
| Sterilization | Gamma Irradiation | 25.0 – 45.0 (kGy) | YES | 2173-34127A |
| Sterility certificate | Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06 | No Growth | Pass | UK23272-1906/MFEP |

| | | |
|---|---|---|
| Diversey | Date of released On behalf of Diversey's Manufacturing location: 09/03/2023 | by : Olga Kirchner<br>Digitally signed by Olga Kirchner DN: cn=Olga Kirchner gn=Olga Kirchner c=GB United Kingdom l=GB United Kingdom o=Flexible Medical Packaging Ltd ou=QA e=olgak@flexible-medical.com Reason: On behalf of FMP Location: Date: 2023-03-09 09:01Z<br>Position: QA Assistance |

The analysis results above could change over time ant in function of the storage temperature. It is imperative to store the products according to the recommended conditions indicated in the SDS.

***End of certificate of analysis***

# STERIS: Gamma Certificate Of Processing

**Prepared for:** FLEXIBLE MEDICAL PACKAGING LTD (8245)

**Gamma Process Run ID** 2173-34127A

| Product Code | Lot Number | Quantity | UOM |
|---|---|---|---|
| TEGO 2000SC DV4724 | FMP23003 - 55625 | 93 | Case |
| Validation Reference Number: | 4724 | | |
| TEGO 2000SC DV4724 | FMP23003 - 55625 1 SAMPLE BOX | 1 | Case |
| Validation Reference Number: | 4724 | | |

**Processing Run Start Date:** 17-Jan-2023 5:42 AM

**Processing Run End Date:** 17-Jan-2023 3:38 PM

| | | | |
|---|---|---|---|
| **Specified Dose Range (kGy):** | **25.0 - 45.0** | **Calculated Min Dose (kGy):** | **28.7** |
| **Reference Dose Range (kGy):** | **29.4 - 40.5** | **Calculated Max Dose (kGy):** | **37.7** |

PO Number: 404283

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

**Gamma Process Run Approval authorized by STERIS**

Date/Time E-Signed: 17-Jan-2023 8:33 PM

**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: Mrs.Olga Kirchner

**Report of Tests on:** Tego 2000SC

**Sample Description:** Sample Code: Fmp23003 55625

**Lucideon Sample Number:** UK23272-1906

**Lucideon Report Number:** UK23272-1906/MFEP **Issue Number:** 1

**Date Logged:** 24-Jan-2023 **Order Number:** 404376

**Date Reported:** 14-Feb-2023 **Date(s) of Test(s):** 26-Jan-2023 **to** 09-Feb-2023

**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**

NC Boot 14 Feb 23

Mrs Natalie Boot
**Senior Business Support Administrator**





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