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### **CERTIFICATE OF ANALYSIS**

Date issue: 23/01/2023

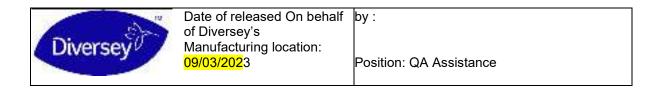
<b>Product Name</b>	DI Tego 2000 S 50x0.05L		
<b>Product Code</b>	101107171		
<b>Batch Number</b>	FMP23005 55633		
<b>Production date</b>	05/01/2023		
<b>Expiration Date</b>	EXP 05/01/2026		

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 (20°C)	DM 004	0.993 - 1.003	g/cm³	1.002
pH (neat Solution	DM 001	7.5 - 8.5	N/A	8.1

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference number
Sterilization	Gamma Irradiation	25.0 – 45.0 (kGy)	YES	2173-34126A
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	<mark>Pass</mark>	UK23272- 1905/MFEP



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\*\*\*

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## STERIS: Gamma Certificate Of Processing

Prepared for:

**FLEXIBLE MEDICAL PACKAGING LTD (8245)** 

Gamma Process Run ID

2173-34126A

**Product Code** 

**Lot Number** 

Quantity **UOM** 

TEGO 2000SC DV4724

FMP23005 - 55633

106 Case

Validation Reference Number:

4724

**TEGO 2000SC DV4724** 

FMP23005 - 55633 1 SAMPLE BOX

Case

Validation Reference Number:

4724

Processing Run Start Date: 17-Jan-2023 5:53 AM

Processing Run End Date: 17-Jan-2023 3:54 PM

Specified Dose Range (kGy):

25.0 - 45.0

Calculated Min Dose (kGy):

29.1

Reference Dose Range (kGy):

29.4 - 40.5

Calculated Max Dose (kGy):

38.9

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 guality 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

Document ID: 13301

Last Revised in Rel 2.0.0.0

Rel Date: 13-Aug-2018

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000SC

**Sample Description:** 

Sample Code: Fmp23005 55633

Lucideon Sample Number: UK23272-1905

Lucideon Report Number: UK23272-1905/MFEP

Issue Number:

Date Logged:

24-Jan-2023

Order Number:

404376

**Date Reported:** 

14-Feb-2023

Date(s) of Test(s):

26-Jan-2023 to 13-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** 

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Mrs Natalie Boot

Senior Business Support Administrator