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## **CERTIFICATE OF ANALYSIS**

Date issue: 23/01/2023

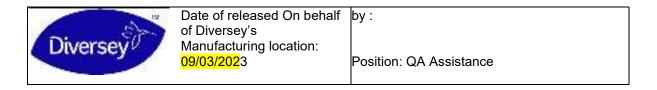
Product Name	I Tego 2000 S 50x0.05L		
Product Code	101107171		
Batch Number	FMP23003 55625		
Production date	03/01/2023		
Expiration Date	EXP 03/01/2026		

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 (20°C)	DM 004	0.993 - 1.003	g/cm <sup>3</sup>	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	<mark>2173-34127A</mark>
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



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\*\*\*

	Pharma COA Template	COA Ph 02	March 2023	Page <b>1</b> of <b>1</b>
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### **STERIS: Gamma Certificate Of Processing**

Prepared for:	FLEXIBLE MEDICAL PACKAGING LTD (8245)
Gamma Process Run ID	2173-34127A

Product Code	Lot Number		<u>Quantity</u>	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-202	3 5:42 AM			
Processing Run End Date: 17-Jan-2023	3 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	e (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



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

14-Feb-2023

Lucideon Sample Number: UK23272-1906

Lucideon Report Number: UK23272-1906/MFEP

Date Logged: 24-Jan-2023

Date Reported:

Order Number:

Date(s) of Test(s):

Sterility Testing Membrane Filtration EP

Issue Number:

404376

1

26-Jan-2023 to 09-Feb-2023

**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

Page 1 of 1

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