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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	FMP23005 55633
Production date	05/01/2023
Expiration Date	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 (20ºC)	DM 004	0.993 – 1.003	g/cm^3	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	Pass	UK23272-1905/MFEP

Date of released On behalf of Diversey's Manufacturing location: 09/03/2023	by : Olga Kirchner Position: QA Assistance 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 09:09Z

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 2173-34126A

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	1	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 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: Fmp23005 55633

Lucideon Sample Number: UK23272-1905

Lucideon Report Number: UK23272-1905/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** 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

NcBoot 14 Feb 23

Mrs Natalie Boot
Senior Business Support Administrator

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