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## **CERTIFICATE OF ANALYSIS**

Date:

24 November 2020

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP20289	50312	
Production Date	15/10/2020		
Expiration Date	EXP 15/10/2023		

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		Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
Specific Gravity (20°C)	DM004	0.993	1.003	1.003
pH (neat solution)	DM001	7.5	8.5	7.5
F== (==================================	24,400	7.5	0.0	710

On behalf of Diversey site Quality Manger	Name:	Justyna Staron	Angelika Partynska
	Position	Quality Control Inspector	

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COA Template Version: 02 Date of issuing: November 24th

# **STERIS: Gamma Certificate Of Processing**

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-15019A

<u>Product Code</u> <u>Lot Number</u> <u>Quantity</u> <u>UOM</u>

TEGO 2000SC DV4724 FMP20289 50312 98 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 FMP20289 50312, SAMPLE BOX 1 Case

Validation Reference Number: 4724

Processing Run Start Date: 12-Nov-20 05:17 AM

Processing Run End Date: 12-Nov-20 12:23 PM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 28.9

Reference Dose Range (kGy): 29.4 - 40.5 Calculated Max Dose (kGy): 38.0

PO Number: 36654

### Gamma Process Run Approval authorized by STERIS

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

Document ID: 64745

Rel Date: 08/13/2018

Last Revised in Rel 2.0.0.0

# PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000 SC

Sample Description:

Sample Code: Fmp20289 50312

Lucideon Sample Number: UK204807-33957

Lucideon Report Number: UK204807-33957/MFEP

Issue Number:

1

Date Logged:

24-Nov-2020

Order Number:

PO36878

Date Reported:

17-Dec-2020

Date(s) of Test(s):

02-Dec-2020 to 16-Dec-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** 

CBOOK IN-DEC-20

Mrs Natalie Boot

Senior Business Support Assistant

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested.

No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation