

Diversey Europe Operations BV Maarssenbroeksedlik 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 08 -08 . 2019

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	10096 1418		
Batch Number	FMP1912C 15HDF		
<b>Production Date</b>	16 OS 2019		
Expiration Date	Exp 16/05/2002		

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 Low	Limits		Results
		Lower	- Upper	
Appearance	Visual	Clear Slightly Yellow Liquid		clear slightly
Specific Gravity (20°C)	DM004	0.993	1.003	1.00)
pH (neat solution)	DM001	7.5	8.5	78

Quality Manager	Position	Quality Control Inspector
On behalf of Diversey site	Name:	7. Hava l. Um Orle

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COA Template	Version: 02	Date of issuing: November 24th 2017

### **STERIS: Gamma Certificate Of Processing**

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4208A

Product CodeLot NumberQuantityUOMTEGO 2000SC DV4724FMP19136 4742775 Case

Validation Reference Number: 4724

TEGO 2000SC DV4724 FMP19136 47427 INC 1 SAMPLE 1 Case

Validation Reference Number: 4724

Processing Run Start Date: 25-Jul-19 08:37 AM
Processing Run End Date: 25-Jul-19 05:15 PM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 30.1 Reference Dose Range (kGy): 29.4-40.5 Calculated Max Dose (kGy): 40.1

### 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: 25347

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 LA1 4XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Tego 2000SC

**Sample Description:** 

Sample Code: Fmp 19136 47427 Batch Ref: 634594

Lucideon Sample Number: (194487)-34816

Lucideon Report Number: (194487)-34816/MFEP

**Issue Number:** 

Date Logged:

09-Aug-2019

**Order Number:** 

PO 33627

**Date Reported:** 

29-Nov-2019

Date(s) of Test(s):

14-Nov-2019 to 28-Nov-2019

**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** 

Mrs Natalie Boot

Senior Business Support Assistant

rBank 29-NOV-19

Page 1 of 1

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 share produced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation