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CERTIFICATE OF ANALYSIS

Date: 04.12.2019

CLEARKLENS TEGO 2000SC VH25		
10090 1119		
ENDIG 200 1151.71		
19713298 , 4841		
CVO 25 HOLD 200		

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	T owner.	nits - Upper	Results
appearance	Visual	Clear Slightly Yellow Liquid		clear sightly
Specific Gravity (20°C)	DM004	0.993	1.003	1.000
pH (neat solution)	DM001	7.5	8.5	7.6

On behalf of Diversey site Quality Manager	Position	Quality Control Inspector
	Name:	M. Staron Pardyest

This document being issued electronically does not bear a signature

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: 2173-6118A

Product Code Lot Number Quantity **UOM TEGO 2000SC DV4724** FMP19298 48471, INC 1 SAMPLE 98 Case

Validation Reference Number: 4724

Processing Run Start Date: 11-Nov-19 01:05 AM Processing Run End Date: 11-Nov-19 08:46 AM

Specified Dose Range (kGy): 25.0 - 45.0 Calculated Min Dose (kGy): 29.6

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

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: 32894

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: Fmp19298 48471

Lucideon Sample Number: (196608)-50136

Lucideon Report Number: (196608)-50136/MFEP

Issue Number:

Date Logged:

05-Dec-2019

Order Number:

PO34403

Date Reported:

23-Dec-2019

Date(s) of Test(s):

06-Dec-2019 to 20-Dec-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

NoBook 23-Dec-19

Senior Business Support Assistant