

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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# **CERTIFICATE OF ANALYSIS**

Date: 23/08/2019

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	100961418
Batch Number	ENP 19205 117 629
Production Date	2410212019
Expiration Date	5KP24102120022

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	Lin Lower -	nits · Upper	Results
Appearance	Visual		tly Yellow uid	Clear Slightic Yellon Lawio
Specific Gravity (20°C)	DM004	0.993	1.003	0.000
pH (neat solution)	DM001	7.5	8.5	77

Quality Manager	Position	Quality Control Inspector
On behalf of Diversey site	Name :	Partyright dema

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COA Template Version : 02 Date of issuing : November 24<sup>th</sup> 2017

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

### Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4546A

Product Code	Lot Number		<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	FMP19205 4	7638	97	Case
Validation Reference Number:	4724			
TEGO 2000SC DV4724	FMP19205 IN	NC 1 SAMPLE	1	Case
Validation Reference Number:	4724			
Processing Run Start Date: 10-Aug-19	08:45 AM			
Processing Run Start Date: 10-Aug-19 Processing Run End Date: 10-Aug-19				
•		Calculated Mi	n Dose (kGy):	30.2

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: Alison Siddle

Report of Tests on: **TEGO 2000 SC** 

Sample Description: Sample Code: FMP19205 47638

Lucideon Sample Number: (194680)-36056

Lucideon Report Number: (194680)-36056/MFEP **Issue Number:** 1 Date Logged: Order Number: 21-Aug-2019 PO33752 Date(s) of Test(s): **Date Reported:** 29-Nov-2019

> **Sterility Testing** Membrane Filtration EP

14-Nov-2019 to 28-Nov-2019

**Test Results:** 

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

**End of Test Report** 

0+ 29-NOV-19

Mrs Natalie Boot Senior Business Support Assistant

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