

Diversey Europe Operations BV Maarasenbroeksedijk 2 3542 DN Utrecht The Netherlands

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## **CERTIFICATE OF ANALYSIS**

Date: 17 June 2020

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	100868202		
Batch Number	FMP20141	50178	
Production Date	20/05/2020		
Expiration Date	EXP 20/05/2023		

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	Limi Lower	its - Upper	Results
Appearance	Visual	Clear Slightly	Yellow Liquid	Clear Slightly Yellow Liquid
Specific Gravity (20°C)	DM004	0.993	1.003	1.001
pH (neat solution)	DM001	7.5	8.5	8.1

On behalf of Diversey site	Name:	Angelika Partynska Urszula Haraburda
Quality Manger	Position	Quality Control Inspector

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COA Template	Version : 02	Date of issuing : November 24th
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## **STERIS: Gamma Certificate Of Processing**

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

Gamma Process Run ID: 2173-11114A

Product Code	FMP20141 50178       50         er:       4724         FMP20141 50178, INC 1 SMPL       18		<u>Quantity</u>	UOM	
TEGO 2000SC DV4724			50	Case	
Validation Reference Number:					
TEGO 2000SC DV4724			18	3 Case	
Validation Reference Number:					
Processing Run Start Date: 06-Jun-20 0	3:58 PM				
Processing Run End Date: 06-Jun-20 1	1:12 PM				
Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dos	se (kGy):	30.3	
Reference Dose Range (kGy):	29.4- 40.5	Calculated Max Dos	se (kGy):	40.8	

PO Number: PO35587

### 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

# 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 2000SCSample Description:Sample Code: Fmp20141 50178Lucideon Sample Number:UK202481-18177

 

 Lucideon Report Number:
 UK202481-18177/MFEP
 Issue Number:
 1

 Date Logged:
 16-Jun-2020
 Order Number:
 PO35688

 Date Reported:
 15-Jul-2020
 Date(s) of Test(s):
 27-Jun-2020
 to
 15-Jul-2020

 Sterility Testing Membrane Filtration EP
 Membrane Filtration EP
 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

15 JUL 20

#### Mrs Andrea Saunders Business Support Assistant

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