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# **CERTIFICATE OF ANALYSIS**

# Date: 15 04 2020

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	100×02 303
Batch Number	FH020085 40101
Production Date	2510312020
Expiration Date	EXP 25/02/2002

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	Limits Lower - Upper		Results	
Appearance	Visual	Clear Slightly Yellow Liquid			
Specific Gravity (20°C)	DM004	0.993	1.003	0000	
pH (neat solution)	DM001	7.5	8.5	4.9	

On behalf of Diversey site	Name :	Marahuda Partyast
Quality Manager	Position	Quality Control Inspector

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

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# **STERIS: Gamma Certificate Of Processing**

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

Gamma Process Run ID: 2173-9571A

Product Code	Lot Number		<u>Quantity</u>	<u>UOM</u>			
TEGO 2000SC DV4724	FMP20085 - \ BOX	FMP20085 - WO49181, INC 1 SAMPLE BOX		Case			
Validation Reference Number: 4724							
Processing Run Start Date: 04-Apr-20 04:07 AM							
Processing Run End Date: 04-Apr-20 11:32 AM							
Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose	e (kGy):	30.7			
Reference Dose Range (kGy):	29.4- 40.5	Calculated Max Dos	e (kGy):	41.0			

PO Number: 35141

## 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: 47351

# 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 2000 SC

Sample Description: Sample Code: Fmp20085 49181

Lucideon Sample Number: UK201733-13631

Lucideon Report Number:	UK201733-13631/MFEP	Issue Number:	1			
Date Logged:	17-Apr-2020	Order Number:	PO 35240			
Date Reported:	13-May-2020	Date(s) of Test(s):	28-Apr-2020 to	12-May-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

NOBOOT 13-MOY-20

Mrs Natalie Boot Senior Business Support Assistant

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