

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date:

17 June 2023

Product Name	CLEARKLENS TEGO 2000SC VH25		
Product Code	101107171		
Batch Number	FMP23145 57980		
Production Date	25/05/2023		
Expiration Date	EXP 25/05/2026		

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
pH (neat solution)	DM001	7.5	8.5	8

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

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COA Template Version : 04 Date of issuing : March 11th 2019		· · · · · · · · · · · · · · · · · · ·	
	COA Template	Version : 04	Date of issuing : March 11th 2019

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID 2173-37919A

Product Code	Lot Number	<u>Qı</u>	uantity	<u>UOM</u>
TEGO 2000SC DV4724	57980		71	Case
Validation Reference Number:	4724			
TEGO 2000SC DV4724	57980, X1 SA	MPLE	1	Case
Validation Reference Number:	4724			
Processing Run Start Date: 13-Jun-2023 10:26 PM				
Processing Run End Date: 14-Jun-2023 6:29 AM				
Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kC	Gy):	31.4
Reference Dose Range (kGy):	29.4 - 40.5	Calculated Max Dose (k	Gy):	41.4

PO Number: 405451

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 14-Jun-2023 8:41 AM

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: 146726

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: Fmp23145 57980 Lucideon Sample Number: UK232264-15424 Lucideon Report Number: UK232264-15424/MFEP **Issue Number:** 1 **Date Logged:** 19-Jun-2023 **Order Number:** 405559 **Date Reported:** 13-Jul-2023 Date(s) of Test(s): 23-Jun-2023 to 11-Jul-2023 **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 Administrator

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