



Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 09 November 2020

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP20300	50194	
Production Date	26/10/2020		
Expiration Date	EXP 26/04/2022		

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		Results
		Lower	Upper	
Appearance	Visual	Clear Slightly Yellow Liquid		Clear Slightly Yellow Liquid
pH (neat solution)	DM001	6.2	8.2	7.6
Specific Gravity (20°C)	DM004	0.980	1.020	0.997

On behalf of Diversey site Quality Manager	Name:	Angelika Partyńska Urszula Haraburda
	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: 2173-14734A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SS BLK1 DV4767	WO50194	59	Case
Validation Reference Number: 4767			
TEGO 2000SS BLK1 DV4767	WO50194, SAMPLE BOXES	3	Case
Validation Reference Number: 4767			

Processing Run Start Date: 04-Nov-20 04:53 AM

Processing Run End Date: 04-Nov-20 12:26 PM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.9
Reference Dose Range (kGy):	31.5 - 39.7	Calculated Max Dose (kGy):	40.2

PO Number: 36699

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

LUCIDEON

insight creating advantage

Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Tego 2000 SS

Sample Description: Sample Code: Fmp20300 50194

Lucideon Sample Number: UK204595-32319

Lucideon Report Number: UK204595-32319/MFEP **Issue Number:** 1

Date Logged: 10-Nov-2020 **Order Number:** PO 36771

Date Reported: 03-Dec-2020 **Date(s) of Test(s):** 18-Nov-2020 to 02-Dec-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



Mrs Andrea Saunders
Business Support Assistant

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Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com