



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 24.07.2020

Product Name	CLEARLENSS TEGO 2000SS VH25S
Product Code	7516427
Batch Number	FMP20183 49735
Production Date	01.07.2020
Expiration Date	EXP 01/01/2022

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	7.7
Specific Gravity (20°C)	DM004	0.990	1.010	0.998

On behalf of Diversey site Quality Manager	Name :	J. Stancu Ionescu
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 th 2017
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-11971A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SS BLK1 DV4767	WO49735	59	Case
Validation Reference Number: 4767			
TEGO 2000SS BLK1 DV4767	WO49735, 3 SAMPLE BOXES	3	Case
Validation Reference Number: 4767			

Processing Run Start Date: 11-Jul-20 02:51 AM

Processing Run End Date: 11-Jul-20 10:28 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	28.9
Reference Dose Range (kGy):	31.5- 39.7	Calculated Max Dose (kGy):	42.3

PO Number: 35885

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

Signature Manifest

Reviewed and E-Signed By: **Bhavya Ramisetty (Quality Engineer)**

Date/Time E-Signed: 2020-07-15 08:12 AM

Document Content Revision: 1

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: Fmp20183 49735

Lucideon Sample Number: UK202949-21082

Lucideon Report Number: UK202949-21082/MFEP **Issue Number:** 1

Date Logged: 21-Jul-2020 **Order Number:** PO 35973

Date Reported: 04-Sep-2020 **Date(s) of Test(s):** 19-Aug-2020 to 02-Sep-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

Natalie Boot 04-Sep-20

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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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