

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 13.08 2018

Product Name	CLEARKLENS TEGO 2000SS VH25S		
Product Code	7516427		
Batch Number	FMP18207 45621		
Production Date	2610412018		
Expiration Date	EXP 26 101 12020		

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	_	ntly Yellow Juid	relians liquid
pH (neat solution)	DM001	6.2	8.2	4.6
Specific Gravity (20°C)	DM004	0.990	1.010	0.996

On behalf of Diversey site Quality Manager	Name :	Il Marchida Partiist
	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
	VC131011 . UZ	Date of issuing . November 24 2017



http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 05-Aug-2018

UK33S12147272-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products EN ISO 13485 Quality System - Medical Devices

Flexible Medical Packaging Ltd Unit 8, White Cross Ind Estate Hightown Lancaster Lancashire LA1 4XS UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information			
Account Number:	100432		
Synergy Health Sales Part Reference:	1111557		
Customer Reference Number:	P031482		
Product Description:	TEGO 2000SS BLK1 DV4767 25-45KGY		
Validation Reference:	4767		
Quantity Received:	179		
Customer Minimum Specification kGy:	25.0		
Customer Maximum Specification kGy:	45.0		
Customer Unit Lot/Batch Number:	FMP18207 45621, INC 5 SMPLS, 4 PLTS		
II	rradiation Data		
Date and Time of Irradiation:	05-Aug-2018 18:16		
Reference Dose Range kGy:	36.0 - 36.3		
Calculated Minimum Dose kGy:	28.6		
Calculated Maximum Dose kGy:	41.2		

Irradiation Release Authorised By Synergy Health Sterillsation UK, a STERIS Company



Wickham Laboratories Ltd Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

Telephone: Fax:

+44(0)1329 226600 +44(0)1329 226688

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA14XS

Date Received:

14 Aug 2018

Date Tested:

22 Aug 2018

Date Test Completed:

05 Sep 2018

Purchase Order:

PO31542

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0044227/1

Test Required:

Sterility by Membrane Filtration Steritest

Date Received:

14/08/2018 Tego 2000SS

Test Article: Sample Code:

FMP18207 45621

Batch Ref:

9557

Qty Received:

20 x 900mL + 3 Spare

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20- 25°C after 14 days	MM107/01	No growth in two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM08-01

Approval is provided by Electronic Signature. Their name and position is shown below.

CBiol, MKSB

Date: 06 Sep 2018 16:02:39

Mrs C Moore

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Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM Consignment: 0044227 Print Number: P0053366

