Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 20/03/2017

Product Name	CLEARKLENS TEGO 2000SS VH25S
Product Code	7516427
Batch Number	FMP 17065 42072
Production Date	06/03/2017
Expiration Date	EXP 06/09/2018

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	Clear Slightly Yellow Liquid
pH 100% (20°C)	JDM001	6.2 - 8.2	7.4
Specific Gravity (20°C)	JDM004	0.990 - 1.010	0.996

On behalf of Diversey site Quality Manager	Name :	Pantyiska, M.
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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Certificate of Irradiation

Date Issued: 10-Mar-2017 **UK33S11828801-2-1**

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
EN ISO 9001:2008 Quality Management System
EN ISO 13485:2012 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:	1106485
Customer Reference Number:	PO28518
Product Description:	TEGO 2000SS BLK1 DV4767 25-45kGy
Validation Reference:	4767
Quantity Received:	63
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17065 42072, INC 4 SAMPLES, 1 PLT

Irradiation Data

Date and Time of Irradiation:	10-Mar-2017 06:16
Reference Dose Range kGy:	35.8 - 36.3
Calculated Minimum Dose kGy:	28.4
Calculated Maximum Dose kGy:	41.2

Irradiation Release Authorised By Synergy Health plc **A2**

Wickham Laboratories
Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
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mail@wickhamlabs.co.uk
www.wickhamlabs.co.uk

Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 21 Mar 2017
Date Tested: 27 Mar 2017
Date Test Completed: 10 Apr 2017
Purchase Order: 28594

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0034562/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 21/03/2017
Test Article: TEGO 2000ss
Sample Code: FMP17065 42072
Batch Ref: 8281
Qty Received: 20 x 900mL Bottles

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	see external comments
Product Standard Data Sheet	FG047/psd	FM08

Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

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

CBiol MRSB

Date: 11 Apr 2017 15:01:12

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA