



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 24.10.2017

Product Name	CLEARKLENS TEGO 2000SS VH25S
Product Code	7516427
Batch Number	FHP 17275-43537
Production Date	02/10/2017
Expiration Date	EXP 02/10/2019

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 100% (20°C)	JDM001	6.2	8.2	4.5
Specific Gravity (20°C)	JDM004	0.990	1.010	0.996

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

This document being issued electronically does not bear a signature

COA VH25S	Version : 05	Date of issuing : June 11 th 2013
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 16-Oct-2017

UK33S11981112-3-1

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:	1111557
Customer Reference Number:	P029723
Product Description:	TEGO 2000SS BLK1 DV4767 25-45KG
Validation Reference:	4767
Quantity Received:	62
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17275 43537, INC 4 SAMPLES, 1 plt

Irradiation Data

Date and Time of Irradiation:	16-Oct-2017 09:44
Reference Dose Range kGy:	35.6 - 35.8
Calculated Minimum Dose kGy:	28.3
Calculated Maximum Dose kGy:	40.6

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069



Wickham Laboratories

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

Date Received: 24 Oct 2017
Date Tested: 31 Oct 2017
Date Test Completed: 14 Nov 2017
Purchase Order: 29849

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0038718/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 24/10/2017
Test Article: Tego 2000SS
Sample Code: FMP17275 43537
Batch Ref: 8826
Qty Received: 20 x 900mL Bottles (+2 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	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: 15 Nov 2017 11:43:13

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology