



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 10/3/14

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	7513387
Batch Number	FMPI4051 35756
Production Date	02/2014
Expiration Date	02/2016

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	7.5	8.5	7.7
Specific Gravity (20°C)	JDM004	0.993	1.003	0.994

On behalf of Diversey site Quality Manager	Name :	Assie, Amakuro
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7513387	Version : 03	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 05-Mar-2014

UK32S11120017-1-1

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

EN ISO 11137-1:2006 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:	1002722
Customer Reference Number:	P021835
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.0716
Quantity Received:	51
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	LOT 2; 1 PLT; THUR 27.02.14; 49 x B/NO. FMP14051 35756 + 2 SAMPLES

Irradiation Data

Date and Time of Irradiation:	05-Mar-2014 12:46
Reference Dose Range kGy:	36.4 - 36.8
Calculated Minimum Dose kGy:	30.2
Calculated Maximum Dose kGy:	40.5

Irradiation Release Authorised By Synergy Health plc

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

Contract Analytical Services

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

Date Received: 10 Mar 2014
Date Tested: 12 Mar 2014
Date Test Completed: 03 Apr 2014
Purchase Order: PO21894

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0015392/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:
PH Eur and USP
Date Received: 10/03/2014
Test Article: TEGO 2000SC Block 1
Sample Code: FMP14051 35756
Batch Ref: 452581
Qty Received: 20 x 50mL 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
Growth of Sub-culture in Tryptone Soya Broth at 30-35°C after 4 days	MM107/07	No growth in two broths
Growth of Sub-culture in Fluid Thioglycollate at 20-25°C after 4 days	MM107/08	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM08

Comments

As Steritest Sterility Test

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

Date: 04 Apr 2014 16:26:15

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0015392

Certificate of Analysis - OSMM

Print Number: P0018872

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ISO
17025

GLP GMP FDA

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