



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 7.4.14

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	7513387
Batch Number	FMP 14070 36005
Production Date	03/2014
Expiration Date	03/2016

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	0.998

On behalf of Diversey site Quality Manager	Name :	Makere A. Boys
	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: 29-Mar-2014

UK32S11131197-1-1

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:	P021948
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.0716
Quantity Received:	105
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	LOT 2; 2 PLTS; THUR 20.03.14; 103 x FMP B/NO. FMP14070 36005 + 2 SAMPLES

Irradiation Data

Date and Time of Irradiation:	29-Mar-2014 10:36
Reference Dose Range kGy:	32.2 - 32.8
Calculated Minimum Dose kGy:	26.7
Calculated Maximum Dose kGy:	36.1

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: 08 Apr 2014
Date Tested: 17 Apr 2014
Date Test Completed: 01 May 2014
Purchase Order: PO22029

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0016006/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 08/04/2014
Test Article: TEGO 2000SC Block 1
Sample Code: FMP14070 36005
Batch Ref: 5233
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
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM08

Comments

Test carried out according to current Pharmacopoeias.

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

Date: 02 May 2014 15:12:00

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0016006

Certificate of Analysis - OSMM

Print Number: P0019607

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ISO
17025

GLP GMP FDA

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