



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 02.11.13

Product Name	CLEARLENSE TEGO 2000SC VH25
Product Code	7514341
Batch Number	FMP 13287 34848
Production Date	10/2013
Expiration Date	10/2015

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	7.5
Specific Gravity (20°C)	JDM004	0.993	1.003	1.001

On behalf of Diversey site Quality Manager	Name :	Makene, P. J. J. J.
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7514341	Version : 03	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 26-Oct-2013

UK32S11064351-1-1

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:	P021180
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.0716
Quantity Received:	246
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	6 PLTS TOTAL ORDER THURS 17.10.13
Other Process Details:	43 + 2 SAMPLES X B/No. FMP13287 34848 , 177 = 2 SAMPLES X B/No. FMP13281 34845 , 20 + 2 SAMPLES X B/No. FMP13285 35188

Irradiation Data

Date and Time of Irradiation:	26-Oct-2013 07:07
Reference Dose Range kGy:	32.5 - 34.0
Calculated Minimum Dose kGy:	27.0
Calculated Maximum Dose kGy:	37.4

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



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

Date Received: 04 Nov 2013
Date Tested: 11 Nov 2013
Date Test Completed: 03 Dec 2013
Purchase Order: 21260

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0013156/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:
PH Eur and USP
Date Received: 04/11/2013
Test Article: TEGO 2000SC Block 2
Sample Code: 447348
Batch Ref: FMP 13287 34848
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 Dec 2013 21:40:58

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0013156

Certificate of Analysis - OSMM

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ISO
17025

GLP GMP FDA

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Registered Office: Winchester Road, Wickham, Fareham, Hampshire