



Diversey Europe BV

Maarssebroeksewijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 3.05.2013

Product Name	CLEARLENSE TEGO 2000SC VH25
Product Code	7513387
Batch Number	FMP 1311234038
Production Date	04/2013
Expiration Date	04/2015

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	7.6
Specific Gravity (20°C)	JDM004	0.993	1.003	0.997

On behalf of Diversey site Quality Manager	Name :	A. Matena
	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
-------------	--------------	--



Wickham Laboratories
contract analytical services

Wickham Laboratories Limited,
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
+44(0)1329 832511
Fax: +44(0)1329 226688

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: 07 May 2013
Date Tested: 15 May 2013
Date Test Completed: 06 Jun 2013
Purchase Order: PO20356

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0010141/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture: PH Eur and USP
Date Received: 07/05/2013
Test Article: TEGO 2000SC Block 1
Sample Code: -
Batch Ref: FMP13112 34038
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 is shown below.

Suz Wood

Date: 10 Jun 2013 16:22:50

Mrs S.L. Wood, BSc (Hons), CBiol, MSB
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0010141

Certificate of Analysis - OSMM

Print Number: P0011114

Page 1 of 1



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 30-Apr-2013

UK32S11016935-1-1

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

ISO 11137:2006 Sterilisation of Health Care Products
 ISO 9001:2008 Quality Management System
 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

Customer Reference Number:	P020325
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.0716
Quantity Received:	127
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	3PLTS LOT 3 THURS 25.4.13
Other Process Details:	104 X B/No.FMP13110/33895 + 2 SAMPLES , 20 X B/No.FMP13112/34038 + 1 SAMPLE
Shop Order Number:	S11016935-1-1
Synergy Health Sales Part Reference:	1002722

Irradiation Data

Date and Time of Irradiation:	30-Apr-2013 07:30
Reference Dose Range kGy:	35.4 - 36.3
Calculated Minimum Dose kGy:	29.4
Calculated Maximum Dose kGy:	39.9

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