



Diversey Europe BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands
Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 12/12/12

Product Name	CLEARLEN S TEGO 2000SC VH25
Product Code	7513387
Batch Number	FMP12328 33084
Production Date	11/2012
Expiration Date	11/2014

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	8.0
Specific Gravity (20°C)	JDM004	0.993	1.003	0.997

On behalf of Diversey site Quality Manager	Name :	
	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: 09-Dec-2012

UK32S11002289-1-1

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 13485:2003 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:	P019571
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.0716
Quantity Received:	104
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	103 X B/No.W033084 CUST/BN0.FMP12328 + 33084. 1 SAMPLE - 2PLTS THURS 29.11.12
Shop Order Number:	S11002289-1-1
Synergy Health Sales Part Reference:	1002722

Irradiation Data

Date and Time of Irradiation:	09-Dec-2012 10:27
Reference Dose Range kGy:	35.0 - 35.4
Calculated Minimum Dose kGy:	29.1
Calculated Maximum Dose kGy:	38.9

Comments:

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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Mr J Jackson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 12 Dec 2012
Date Tested: 13 Dec 2012
Date Test Completed: 04 Jan 2013
Purchase Order: 19623

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0008047/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture: PH Eur and USP
Date Received: 12/12/2012
Test Article: TEGO 2000SC Block 1
Sample Code: FMP12328 33084
Batch Ref: 423600
Qty Received: 20 x 50mL bottles + 5 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
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.

Date: 08 Jan 2013 09:46:05

Mrs P. Pham-Lengoc, BSc, MSB
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0008047

Certificate of Analysis - OSMM

Print Number: P0007872

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