



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 25/11/14

Product Name	CLEARLEN S TEGO 2001SC VH24
Product Code	7517177
Batch Number	FMP14300 37273
Production Date	10/2014
Expiration Date	10/2016

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	8.5	9.5	8.9
Specific Gravity (20°C)	JDM004	1.040	1.080	1.058

On behalf of Diversey site Quality Manager	Name :	Maureen, Opa Linche
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7517177

Version : 02

Date of issuing : November 28th 2011



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 19-Nov-2014

UK32S11273397-1-1

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:	1002723
Customer Reference Number:	P023226
Product Description:	DIVERSEY TEGO2001 10x5x100 25-42kGy
Validation Reference:	4.0706
Quantity Received:	101
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	B/N FMP14300 37273 + 1 SAMPLE THUR 06.11.14 2 PLTS LOT 3
Other Process Details:	Released against validation 4.1852. Calculated minimum dose 26.3 kGy and calculated maximum dose 39.3 kGy

Irradiation Data

Date and Time of Irradiation:	15-Nov-2014 17:14
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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

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

Date Received: 24 Nov 2014
Date Tested: 27 Nov 2014
Date Test Completed: 19 Dec 2014
Purchase Order: 23348

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0019924/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:
PH Eur and USP
Date Received: 24/11/2014
Test Article: TEGO 2001sc
Sample Code: 484462
Batch Ref: FMP14300 37273
Qty Received: 20 x 100mL 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 one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Growth of Sub-culture in Tryptone Soya Broth at 30-35°C after 4 days	MM107/07	No growth in one broth
Growth of Sub-culture in Fluid Thioglycollate at 20-25°C after 4 days	MM107/08	No growth in one broth
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM09

Comments

Test carried out according to current Pharmacopoeias.

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

Date: 23 Dec 2014 14:11:29

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0019924

Certificate of Analysis - OSMM

Print Number: P0024642

Page 1 of 1

ISO
17025

GLP GMP FDA

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