



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 19.05.15

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	7513387
Batch Number	FRP 15099 37915
Production Date	14/04/2015
Expiration Date	14/04/2018

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	0.994

On behalf of Diversey site Quality Manager	Name :	Pauyesshe Okechwa
	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
-------------	--------------	--



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 11-May-2015

UK32S11373121-1-1

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:	PO24180
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.0716
Quantity Received:	102
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	101 X FMP15099 37915 + 1 SAMPLE THURS 16 APR 2015 2PLTS LOT 1
Other Process Details:	Released against validation 4.1970. Calculated minimum dose 28.7 kGy and calculated maximum dose 40.4 kGy.

Irradiation Data

Date and Time of Irradiation:	09-May-2015 00:22
-------------------------------	-------------------

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

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

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: 13 May 2015
Date Tested: 20 May 2015
Date Test Completed: 11 Jun 2015
Purchase Order: 24343

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0022636/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method with Subculture:
PH Eur and USP
Date Received: 13/05/2015
Test Article: Tego 2000sc
Sample Code: -
Batch Ref: FMP15099 37915
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 TSB at 20-25°C after 4 - 7 days	MM107/07	No growth in two broths
Growth of Sub-culture in THY at 30-35°C after 4 - 7 days	MM107/08	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM08

Comments

See PHM 2015 126

Test carried out according to current Pharmacopoeias.

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

Date: 12 Jun 2015 14:51:49

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0022636

Certificate of Analysis - OSMM

Print Number: P0027708

Page 1 of 1

ISO
17025

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Hoeford Point, Barwell Lane, Gosport, Hampshire