



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 22.9.15

Product Name	CLEARLENs TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP 15241 39136
Production Date	29/08/2015
Expiration Date	29/08/2018

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	7.8
Specific Gravity (20°C)	JDM004	0.993	1.003	0.998

On behalf of Diversey site Quality Manager	Name :	J. Staan
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7513387	Version : 04	Date of issuing : April 27 th 2012
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 16-Sep-2015

UK32S11460509-1-1

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

EN ISO 11137-1:2015 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:	PO25054
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.1970
Quantity Received:	106
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	THURS 3RD SEPT 2015 3 PLTS LOT 1
Other Process Details:	68 X BATCH NO: FMP15237 38699 + 1 SAMPLE 36 X BATCH NO: FMP15241 39136 + 1 SAMPLE

Irradiation Data

Date and Time of Irradiation:	16-Sep-2015 09:28
Reference Dose Range kGy:	34.0 - 34.6
Calculated Minimum Dose kGy:	27.6
Calculated Maximum Dose kGy:	38.2

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

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
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: 21 Sep 2015
Date Tested: 26 Sep 2015
Date Test Completed: 10 Oct 2015
Purchase Order: 25146

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0024811/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:
PH Eur and USP
Date Received: 21/09/2015
Test Article: TEGO 2000sc
Sample Code: FMP15241 39136
Batch Ref: 505145
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

Test carried out according to current Pharmacopoeias.

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

Date: 13 Oct 2015 14:15:48

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology