



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 4.12.2015

Product Name	CLEARLENs TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP 15316 39401
Production Date	12/11/2015
Expiration Date	EXP 12/11/2018

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	7.9
Specific Gravity (20°C)	JDM004	0.993	1.003	0.998

On behalf of Diversey site Quality Manager	Name :	Parvinder, H. H.
	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: 29-Nov-2015

UK32S11510744-1-1

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:	P025510
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.1970
Quantity Received:	88
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	THURS 19TH NOV 2015 3 PLTS LOT 1
Other Process Details:	67 X BATCH NO. FMP15316 39401 + 1 SAMPLE, 19 X BATCH NO. FMP15315 39058 + 1 SAMPLE

Irradiation Data

Date and Time of Irradiation:	28-Nov-2015 23:34
Reference Dose Range kGy:	33.8 - 34.9
Calculated Minimum Dose kGy:	27.4
Calculated Maximum Dose kGy:	38.5

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

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

Date Received: 07 Dec 2015
Date Tested: 14 Dec 2015
Date Test Completed: 28 Dec 2015
Purchase Order: PO25598

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0026228/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 07/12/2015
Test Article: TEGO 2000sc
Sample Code: -
Batch Ref: FMP 15316 39401
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
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: 29 Dec 2015 14:14:03

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology