



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 22.10.15

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP 15275 38954
Production Date	02.10.2015
Expiration Date	EXP 02.10.2018

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 Yellow Slightly Liquid
pH 100% (20°C)	JDM001	7.5	8.5	8.0
Specific Gravity (20°C)	JDM004	0.993	1.003	0.998

On behalf of Diversey site Quality Manager	Name :	Y. Stawon, P. Kyska
	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: 19-Oct-2015

UK32S11485320-1-1

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:	P025280
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.1970
Quantity Received:	211
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	TUES 13TH OCT 2015 4 PLTS + 2 SAMPLES
Other Process Details:	104 X BATCH NO: FMP15275 38954 + 1 SAMPLE, 105 X BATCH NO: FMP15281 39057 + 1 SAMPLE

Irradiation Data

Date and Time of Irradiation:	18-Oct-2015 10:30
Reference Dose Range kGy:	33.5 - 35.6
Calculated Minimum Dose kGy:	27.2
Calculated Maximum Dose kGy:	39.3

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: 22 Oct 2015
Date Tested: 03 Nov 2015
Date Test Completed: 17 Nov 2015
Purchase Order: 25335

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0025445/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 22/10/2015
Test Article: TEGO 2000sc
Sample Code: 512468
Batch Ref: FMP 15275 38954
Qty Received: 20 x 50mL Bottles

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: 18 Nov 2015 15:48:51

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology