



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 26/1/16

Product Name	CLEARLENSE TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP15344 39567
Production Date	10/12/2015
Expiration Date	EXP 10/12/2018

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 l.g.v.d
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 :	C. M. Scaer, Partyisha
	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: 17-Jan-2016

UK32S11539586-1-1

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:	P025731
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.1970
Quantity Received:	105
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	BATCH NO: FMP15344 39567 THURS 7TH JAN 2016 2 PLTS + 1 SAMPLE

Irradiation Data

Date and Time of Irradiation:	16-Jan-2016 19:03
Reference Dose Range kGy:	35.1 - 35.1
Calculated Minimum Dose kGy:	28.5
Calculated Maximum Dose kGy:	38.8

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: 25 Jan 2016
Date Tested: 02 Feb 2016
Date Test Completed: 24 Feb 2016
Purchase Order: 25846

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0026908/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:
PH Eur and USP
Date Received: 25/01/2016
Test Article: TEGO 2000sc
Sample Code: FMP15344 39567
Batch Ref: 518692
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: 26 Feb 2016 12:21:08

Mr K.A. Barker
Business Manager – Projects