



Diversey Europe BV

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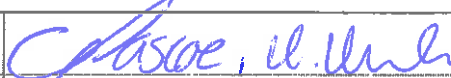
CERTIFICATE OF ANALYSIS

Date: 22/3/16

Product Name	CLEARKLENS TEGO 2000SC VH25
Product Code	7513387
Batch Number	FMP16067 40172
Production Date	07/03/2016
Expiration Date	07/03/2019

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	8.0
Specific Gravity (20°C)	JDM004	0.993	1.003	0.999

On behalf of Diversey site Quality Manager	Name :	
	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
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Certificate of Irradiation

Date Issued: 12-Mar-2016

UK32S11581589-1-1

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:	P026164
Product Description:	DIVERSEY TEGO 2000SC 50ml 25-42kGy
Validation Reference:	4.1970
Quantity Received:	104
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	THURS 10TH MAR 2016 3 PLTS LOT 2
Other Process Details:	73 X FMP BATCH NO: FMP16063 39964 + 1 SAMPLE, 29 X FMP BATCH NO: FMP16067 40172 + 1 SAMPLE

Irradiation Data

Date and Time of Irradiation:	12-Mar-2016 11:14
Reference Dose Range kGy:	33.8 - 35.1
Calculated Minimum Dose kGy:	27.4
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

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

Date Received: 21 Mar 2016
Date Tested: 24 Mar 2016
Date Test Completed: 07 Apr 2016
Purchase Order: 26225

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0027985/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 21/03/2016
Test Article: TEGO 2000sc
Sample Code: FMP16067 40172
Batch Ref: 518692
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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 8.0 2.6.1, USP 38 <71> & JP XVI 4.06
Product Standard Data Sheet	FG047/psd	FM08

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

Date: 08 Apr 2016 14:56:12

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology