



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 2.04.16

Product Name	CLEARKLENS TEGO 2001SC VH24
Product Code	7517177
Batch Number	FMP 16067 - 40068
Production Date	04/03/2016
Expiration Date	EXP 04/03/2018

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	8.5	9.5	8.8
Specific Gravity (20°C)	JDM004	1.040	1.080	1.059

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

This document being issued electronically does not bear a signature

COA 7517177	Version : 02	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 21-Mar-2016

UK32S11586161-1-1

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:	1002723
Customer Reference Number:	P026218
Product Description:	DIVERSEY TEG02001 10x5x100 25-42kGy
Validation Reference:	4.1852
Quantity Received:	101
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	100 X BATCH NO: FMP16067 40068 + 1 SAMPLE THURS 17TH MAR 2016 2 PLTS LOT 2

Irradiation Data

Date and Time of Irradiation:	20-Mar-2016 04:36
Reference Dose Range kGy:	33.6 - 34.1
Calculated Minimum Dose kGy:	26.3
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

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: 31 Mar 2016
Date Tested: 12 Apr 2016
Date Test Completed: 26 Apr 2016
Purchase Order: 26265

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0028157/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 31/03/2016
Test Article: TEGO 2001sc
Sample Code: FMP16067 40068
Batch Ref: 526802
Qty Received: 20 x 100mL 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 one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
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	FM09

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

Date: 27 Apr 2016 14:18:42

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology