



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 9.11.2017

Product Name	CLEARKLENS TEGO 2001SC VH24
Product Code	7517177
Batch Number	FMP17244 43291
Production Date	01/09/2017
Expiration Date	EXP 01/09/2019

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	8.5	9.5	8.7
Specific Gravity (20°C)	JDM004	1.040	1.080	1.060

On behalf of Diversey site Quality Manager	Name :	Kawabuda J. Staver
	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: 11-Sep-2017

UK33S11957580-2-1

This is to certify that AST Daventry 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:	1109782
Customer Reference Number:	P029570
Product Description:	TEGO 2001 SC SOLUTION 100ML DV4856 25-45kGy
Validation Reference:	4856
Quantity Received:	107
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17244 43291, INCLUDING 7 SAMPLES, 2PLTS

Irradiation Data

Date and Time of Irradiation:	10-Sep-2017 18:35
Reference Dose Range kGy:	35.0 - 36.1
Calculated Minimum Dose kGy:	27.7
Calculated Maximum Dose kGy:	39.6

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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
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Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 09 Nov 2017
Date Tested: 15 Nov 2017
Date Test Completed: 05 Dec 2017
Purchase Order: 29938

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0039059/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 09/11/2017
Test Article: Tego 2001SC
Sample Code: FMP17244 43291
Batch Ref: 585315
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
Growth of Sub-culture in TSB at 20-25°C after 4 - 7 days	MM107/07	No growth in one broth
Growth of Sub-culture in THY at 30-35°C after 4 - 7 days	MM107/08	No growth in one broth
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM09

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

 CBIOL MRSB

Date: 06 Dec 2017 14:37:07

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology