



Diversey Europe BV

Maarssebroekseedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 27.10.16

Product Name	CLEARLENSE TEGO 2000SC VH25
Product Code	7513387
Batch Number	FMP 16258 41277
Production Date	14/09/2016
Expiration Date	EXP 14/09/2019

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	7.5	8.5	7.9
Specific Gravity (20°C)	JDM004	0.993	1.003	1.000

On behalf of Diversey site Quality Manager	Name :	Parvinder J. Stawon
	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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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: 25 Oct 2016
Date Tested: 01 Nov 2016
Date Test Completed: 21 Nov 2016
Purchase Order: 27543

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0031868/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 25/10/2016
Test Article: TEGO 2000sc
Sample Code: -
Batch Ref: FMP16258 41277
Qty Received: 20 x 50mL Bottles (+10 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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 8.0 2.6.1, USP 39 <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: 22 Nov 2016 12:06:42

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 14-Oct-2016

UK33S11712670-1-1

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:	1106751
Customer Reference Number:	P027369
Product Description:	TEGO 2000SC DV4724 25-45 kGy
Validation Reference:	4724
Quantity Received:	102
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	DEV000902, FMP16258 41277, Inc 2 Samples, 2 plts

Irradiation Data

Date and Time of Irradiation:	14-Oct-2016 07:22
Reference Dose Range kGy:	36.3 - 36.8
Calculated Minimum Dose kGy:	30.8
Calculated Maximum Dose kGy:	40.9

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