



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 6.09.16

Product Name	CLEARLENs TEGO 2000SC VH25
Product Code	7513387
Batch Number	FMP 16 202 - 41219
Production Date	2010412016
Expiration Date	2010412019

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	1.000

On behalf of Diversey site Quality Manager	Name :	H. Kunk, J. Stauon
	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: 07 Sep 2016
Date Tested: 16 Sep 2016
Date Test Completed: 05 Oct 2016
Purchase Order: 27278

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0030973/3
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 07/09/2016
Test Article: TEGO 2000sc
Sample Code: -
Batch Ref: FMP16202 41219
Qty Received: 20 x 50mL Bottles (+ 20 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: 06 Oct 2016 16:17:29

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 29-Aug-2016

UK33S11689892-1-2

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:	P027047
Product Description:	TEGO 2000SC DV4724 25-45 kGy
Validation Reference:	4724
Quantity Received:	98
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	FMP BATCH NO: FMP16202, 41219, INC 1 SAMPLE BOX, 2 PLTS

Irradiation Data

Date and Time of Irradiation:	29-Aug-2016 05:44
Reference Dose Range kGy:	36.7 - 37.4
Calculated Minimum Dose kGy:	31.2
Calculated Maximum Dose kGy:	41.6

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