



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 23.02.2017

Product Name	CLEARLENSE TEGO 2000SC VH25
Product Code	7513387
Batch Number	FMP17026, 41868
Production Date	26/01/2017
Expiration Date	EXP 26/01/2020

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. Lindert Parys
	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

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

Date Received: 22 Feb 2017
Date Tested: 13 Mar 2017
Date Test Completed: 27 Mar 2017
Purchase Order: PO28441

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0034016/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 22/02/2017
Test Article: ClearKlens TEGO 2000sc
Sample Code: FMP17026 41868
Batch Ref: 557867
Qty Received: 20 x 50mL Bottles + 5 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
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 39 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM08

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

Date: 28 Mar 2017 11:32:43

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 15-Feb-2017

UK33S11808300-1-1

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:	P028309
Product Description:	TEGO 2000SC DV4724 25-45 kGy
Validation Reference:	4724
Quantity Received:	105
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17026 41868, inc 1 sample box, 2 plts

Irradiation Data

Date and Time of Irradiation:	15-Feb-2017 21:17
Reference Dose Range kGy:	33.3 - 34.1
Calculated Minimum Dose kGy:	28.3
Calculated Maximum Dose kGy:	37.9

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