



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 30/10/2018

Product Name	CLEARLEN S TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP 18284 46024
Production Date	11/10/2018
Expiration Date	EXP 11/10/2021

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
Specific Gravity (20°C)	DM004	0.993	1.003	1.000
pH (neat solution)	DM001	7.5	8.5	7.6

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

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 th 2017
--------------	--------------	--



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 Oct 2018
Date Tested: 08 Nov 2018
Date Test Completed: 27 Nov 2018
Purchase Order: 32019

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0045550/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 31/10/2018
Test Article: Tego 2000SC
Sample Code: FMP18284 46024
Batch Ref: 610092
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
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 9.0 2.6.1, USP 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM08-02

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

BSc, CBiol. MRSP

Date: 29 Nov 2018 11:51:33

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 24-Oct-2018

UK33S12184414-3-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	P031918
Product Description:	TEGO 2000SC DV4724 25-45 kGy Validation
Reference:	4724
Quantity Received:	61
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18284 46024, INC 1 SMPL, 1 PLT

Irradiation Data

Date and Time of Irradiation:	24-Oct-2018 04:05
Reference Dose Range kGy:	34.8 - 35.0
Calculated Minimum Dose kGy:	29.6
Calculated Maximum Dose kGy:	38.9

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

A2

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