



Diversey Europe BV

Maarssebroekseeljk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 7.08.2015

Product Name	CLEARLEN S TEGO 2001SC VH24
Product Code	7517177
Batch Number	FMP 15199 38649
Production Date	18/07/2015
Expiration Date	18/07/2017

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	8.9
Specific Gravity (20°C)	JDM004	1.040	1.080	1.054

On behalf of Diversey site Quality Manager	Name :	Olga Lachna, Pantylova
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7517177	Version : 02	Date of issuing : November 28 <sup>th</sup> 2011
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 03-Aug-2015

UK32S11435736-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 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

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## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1002723
Customer Reference Number:	PO24822
Product Description:	DIVERSEY TEGO2001 10x5x100 25-42kGy
Validation Reference:	4.1852
Quantity Received:	101
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	42.0
Customer Unit Lot/Batch Number:	B/NO: FMP15199 38649 TUES 28 JULY 2015 2PLTS LOT 3 + 1 SAMPLE

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## Irradiation Data

Date and Time of Irradiation:	01-Aug-2015 18:48
Reference Dose Range kGy:	32.1 - 33.4
Calculated Minimum Dose kGy:	25.1
Calculated Maximum Dose kGy:	38.0

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Irradiation Release Authorised By Synergy Health plc

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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

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:** 10 Aug 2015  
**Date Tested:** 19 Aug 2015  
**Date Test Completed:** 02 Sep 2015  
**Purchase Order:** PO24895

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0024104/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 10/08/2015  
**Test Article:** ClearKlens Tego 2001sc  
**Sample Code:**  
**Batch Ref:** FMP15199 38649  
**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
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM09

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 03 Sep 2015 15:57:33

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology