



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 11/12/14

Product Name	CLEARKLENS TEGO 2001SS VH24S
Product Code	7513403
Batch Number	FMP14318 37239
Production Date	11/2014
Expiration Date	09/2015

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	8.0	9.0	8.7
Specific Gravity (20°C)	JDM004	0.980	1.020	0.998

On behalf of Diversey site Quality Manager	Name :	<i>C. M. Sloe</i>
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7513403	Version : 04	Date of issuing : April 19 <sup>th</sup> 2012
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 17-Dec-2014

UK31S11290020-1-1

This is to certify that Elgin 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

Synergy Intersite - Bradford  
 Roydsdale Way,  
 Euroway Trading Estate  
 Bradford  
 Yorkshire BD4 6SE  
 UNITED KINGDOM

## Order Information

Account Number:	UK32
Synergy Health Sales Part Reference:	1087099
Customer Reference Number:	S11281594
Product Description:	TEGO 2001 SS 2.0-7.0kGy
Quantity Received:	131
Customer Minimum Specification kGy:	2.0
Customer Maximum Specification kGy:	7.0
Customer Unit Lot/Batch Number:	SINGLE VALIDATION, DOSE REQ: 2.0-7.0 kGy, LOT: FMP14318 37239, 340X280X220 @ 6.6KG
Other Process Details:	TOP UP FOR S11281594, VALIDATION REF NO 5.1017 ACTUAL MIN:2.2 MAX: 3.0KGY

## Irradiation Data

Date and Time of Irradiation:	04-Dec-2014 05:21
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Irradiation Release Authorised By Synergy Health plc

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



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 24-Dec-2014

UK32S11281594-1-1

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

## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1002758
Customer Reference Number:	PO 23331
Product Description:	TEGO 2001 SS 25-45kGy
Validation Reference:	4.0968
Quantity Received:	131
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	129 X FMP14318 37239 + 2 SAMPLES THURS 20.11.14 3PLTS LOT 3
Other Process Details:	Product originally received an under-dose of 1.0 kGy (as shown below) and was subsequently sent for dose augmentation at the Elgin Site 04 Dec 2014, NC ref 541. Actual augmented dose recieved = minimum 2.2 kGy and maximum 3.0 kGy (S11290020). Total certifiable dose = minimum 26.2 kGy and maximum 41.0 kGy

## Irradiation Data

Date and Time of Irradiation:	23-Nov-2014 05:12
Reference Dose Range kGy:	33.6 - 35.2
Calculated Minimum Dose kGy:	24.0
Calculated Maximum Dose kGy:	38.0

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