



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 31.1.14

Product Name	CLEARKLENS TEGO 2001SS VH24S
Product Code	7513403
Batch Number	FMP 14021, 35490
Production Date	01/2014
Expiration Date	11/2014

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 :	Amara Panty Eiso
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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

Certificate of Irradiation

Date Issued: 29-Jan-2014

UK32S11102637-1-1

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:	P021657
Product Description:	TEGO 2001 SS 25-45kGy
Validation Reference:	4.0968
Quantity Received:	133
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	LOT 2; 3 PLTS; THUR 23.01.14; 128 x B/NO. FMP14021 35490 + 5 SAMPLES

Irradiation Data

Date and Time of Irradiation:	29-Jan-2014 05:40
Reference Dose Range kGy:	35.5 - 37.1
Calculated Minimum Dose kGy:	25.4
Calculated Maximum Dose kGy:	40.0

Irradiation Release Authorised By Synergy Health plc



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
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mail@wickhamlabs.co.uk
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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 03 Feb 2014
Date Tested: 05 Feb 2014
Date Test Completed: 27 Feb 2014
Purchase Order: 21702

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0014658/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:
PH Eur and USP
Date Received: 03/02/2014
Test Article: Tego 2001SS Block 1
Sample Code: FMP14021 35490
Batch Ref: 456427
Qty Received: 20 x 900mL 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
Growth of Sub-culture in Tryptone Soya Broth at 30-35°C after 4 days	MM107/07	No growth in one broth
Growth of Sub-culture in Fluid Thioglycollate at 20-25°C after 4 days	MM107/08	No growth in one broth
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM09

Comments

As Steritest Sterility Test

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

Date: 28 Feb 2014 14:29:28

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0014658

Certificate of Analysis - OSMM

Print Number: P0017932

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ISO
17025

GLP GMP FDA

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