



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 11.11.13

Product Name	CLEARKLENS TEGO 2000SS VH25S
Product Code	7516427
Batch Number	FMP 13287 34711
Production Date	10/2013
Expiration Date	04/2015

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	7.3	8.2	7.3
Specific Gravity (20°C)	JDM004	0.990	1.010	0.993

On behalf of Diversey site Quality Manager	Name :	Maheux, O. Lichner
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516427	Version : 03	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 20-Nov-2013

UK32S11065453-1-1

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:	1035147
Customer Reference Number:	P021180
Product Description:	TEGO 2000SS BLK1 25-45KGy
Validation Reference:	4.0621
Quantity Received:	145
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	LOT 2, 4 PLTS, TUE 22.10.13
Other Process Details:	67 x FMP13287 34710 + 5 SAMPLES, 68 x FMP13287 34711 + 5 SAMPLES

Irradiation Data

Date and Time of Irradiation:	01-Nov-2013 15:57
Reference Dose Range kGy:	35.9 - 36.5
Calculated Minimum Dose kGy:	25.8
Calculated Maximum Dose kGy:	38.7

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



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: 11 Nov 2013
Date Tested: 20 Nov 2013
Date Test Completed: 12 Dec 2013
Purchase Order: 21290

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0013285/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:
PH Eur and USP
Date Received: 11/11/2013
Test Article: TEGO 2000SS Block 1
Sample Code: FMP13287 34711
Batch Ref: 4696
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 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 Tryptone Soya Broth at 30-35°C after 4 days	MM107/07	No growth in two broths
Growth of Sub-culture in Fluid Thioglycollate at 20-25°C after 4 days	MM107/08	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM08

Comments

As Steritest Sterility Test

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

Date: 13 Dec 2013 18:32:47

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

Consignment: 0013285

Certificate of Analysis - OSMM

Print Number: P0016077

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ISO
17025

GLP GMP FDA

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