



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 6.07.2016

Product Name	CLEARLENSS TEGO 2000SS VH25S
Product Code	7516427
Batch Number	FHP 16 168 40776
Production Date	16/06/2016
Expiration Date	Exp. 16/12/2017

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	6.2	8.2	7.5
Specific Gravity (20°C)	JDM004	0.990	1.010	0.996

On behalf of Diversey site Quality Manager	Name :	O. Kinnear, Portyridh
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA VH25S	Version : 05	Date of issuing : June 11 th 2013
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Wickham Laboratories

Contract Analytical Services

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Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
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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: 07 Jul 2016
Date Tested: 12 Jul 2016
Date Test Completed: 26 Jul 2016
Purchase Order: 26897

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029865/3
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 07/07/2016
Test Article: TEGO 2000ss
Sample Code: FMP16168 40776
Batch Ref: 7672
Qty Received: 20 X 900mL Bottles + 2 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
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	See external comments
Product Standard Data Sheet	FG047/psd	FM08

Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

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

Date: 27 Jul 2016 15:42:46

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 02-Jul-2016

UK32S11652033-1-1

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

EN ISO 11137-1:2015 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:	P026778
Product Description:	TEGO 2000SS BLK1 25-45KG
Validation Reference:	4.1903
Quantity Received:	62
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	58 X BATCH NO: FMP16168 40776 + 4 SAMPLES THURS 23RD JUNE 2016 1 PLT LOT 2

Irradiation Data

Date and Time of Irradiation:	01-Jul-2016 22:28
Reference Dose Range kGy:	36.8 - 38.2
Calculated Minimum Dose kGy:	26.0
Calculated Maximum Dose kGy:	40.0

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

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



Solutions in Healthcare Contract
Manufacture & Packing

VAT Registration No: GB 534 5276 43

CERTIFICATE OF CONFORMANCE

Flexible Medical Packaging Ltd
Unit 8, Hightown
White Cross Industrial Estate
Lancaster
Lancashire, LA1 4XS

01524 68737
01524 67110
sales@flexible-medical.com
www.flexible-medical.com



TO:
Diversey Ltd
Amber Park Distribution Centre
Highview Road
South Normanton, Alfreton
Derbyshire
DE55 2DT

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DATE : 10/08/16
DESPATCH NO : DN36604
FMP ORDER NUMBER : SO28143
CUSTOMER REFERENCE : 4701872590/7516427

LINE	PART NUMBER	CUSTOMER REFERENCE	QUANTITY	UNIT	LOT REF	LOT LINE
=====	=====	=====	=====	=====	=====	=====
1	DEV001783	7516427	58	EA	WO40776	
	CLEARLENSS TEGO 2000SS 900ML - BLOCK 1					
	BATCH NO: FMP16168 40778					
	Labelled with UN LQ					
	ENVIROWASTE - 6 UNT CASE - 568.5G - PLASTIC					
	DAVENTRY VALI REQ					

CERTIFICATE OF CONFORMANCE

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These goods have been manufactured in accordance with FMP Quality Systems (ISO9001:2008, ISO13485:2003, ISO14001:2004) and to the agreed specification. Responsibility for release of sterile products remains with the customer. Customers are responsible for ensuring the fitness for the purpose of the goods supplied.

FOR AND ON BEHALF OF FMP Q.A. DEPARTMENT: *C. Price*

DATE: 16/08/16

