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CERTIFICATE OF ANALYSIS

Date: 03/12/2020

Product Name	CLEARLEN S TEGO 2000SC VH25
Product Code	100868202
Batch Number	FMP 20310 50954
Production Date	05/11/2020
Expiration Date	Exp 05/11/2023

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	Clear slightly Yellow Liquid
Specific Gravity (20°C)	DM004	0.993	1.003	1.001
pH (neat solution)	DM001	7.5	8.5	7.8

On behalf of Diversey site Quality Manager	Name :	A. Bony, J. Stawow
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of Issuing : November 24 th 2017
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-15108A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TEGO 2000SC DV4724	WO50954	37	Case
Validation Reference Number: 4724			
TEGO 2000SC DV4724	WO50954, SAMPLE BOX	1	Case
Validation Reference Number: 4724			

Processing Run Start Date: 19-Nov-20 03:11 AM

Processing Run End Date: 19-Nov-20 10:48 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	29.3
Reference Dose Range (kGy):	29.4 - 40.5	Calculated Max Dose (kGy):	40.0

PO Number: 36803

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By: **Nelia Dias (Quality Engineer)**

Date/Time E-Signed: 2020-11-20 09:46 AM

Document Content Revision: 1

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK
Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Tego 2000 SC

Sample Description: Sample Code: Fmp20310 50954

Lucideon Sample Number: UK204945-34351

Lucideon Report Number: UK204945-34351/MFEP **Issue Number:** 1

Date Logged: 03-Dec-2020 **Order Number:** PO 36957

Date Reported: 16-Feb-2021 **Date(s) of Test(s):** 27-Jan-2021 to 14-Feb-2021

Sterility Testing

Membrane Filtration EP

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

Natalie Boot 16 Feb - 21

Mrs Natalie Boot

Business Support Administrator

Page 1 of 1

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