DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	2/10/2025-2/13/2025
	FEI NUMBER 3006892175

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Julija Shabanova, Executive Director QA/RA

FIRM NAME	STREET ADDRESS
Tristel Solutions Limited	Unit 1b, Lynx Business Park, Fordham Road
CITY, STATE, ZIP CODE, COUNTRY Snailwell, Cambridgeshire, CB8 7NY United Kingdom	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically, during your effectiveness check of CAPA001, a spot check audit was conducted on 2 Dec 2024, and revealed that your QC Analyst did not use the required document QT1138 during release activities. The QC Analyst was trained on this new document, QT1138, on 2 Oct 2024. CAPA001 was closed as effective, even though your QC Analyst did not use the proper document, per their training.

Additionally, your procedure Nonconformity, Concession and CAPA Procedure, Document No. 520, revision 12, effective 17 May 2024, does not have procedures for handling ineffective verification activities for CAPAs.

OBSERVATION 2

Products that do not conform to specifications are not adequately controlled.

Specifically, during a packaging validation study, VAL1618, your firm received finished product from your contract manufacturer. The product received was found to be leaking due to inadequate tightening of the caps by your contract manufacturer. Per your Supplier Complaint Procedure, Document No. 591,

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Melanie W Pishnery, Investigator X Melanie W Pishnery Investigator Signed By: Melanie W. Pishnery -S Date Signed: 02-13-2025 13:57:25	2/13/2025

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revision 3, effective 20 Nov 2023, a supplier complaint should have been raised for the damaged packaging and loose caps. Additionally, your Supplier Complaint procedure requires a nonconformance to be initiated as well; however, a supplier complaint and nonconformance were not raised for this issue.

OBSERVATION 3

The results of design validation, including method(s), were not documented in the design history file.

Specifically, four laboratory studies (GLP 2012, 2013, 2014, and 2015) were conducted to determine the ability of your product, Tristel Duo and Duo Wipes, to sufficiently disinfect patient-contaminated ultrasound probes. The study criteria specified a contact time for the product as [(b)(4)] with a tolerance of [(b)(4)] The reports only document confirmation the contact time was met; however the data showing actual contact time during the studies could not be provided.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

~~Under consideration~~

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."