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	3/16/2026-3/19/2026
	FEI NUMBER 3003675041

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marie Bertrand, Managing Director

FIRM NAME	STREET ADDRESS
Surgical Instruments Belgium SA (SIBEL S.A.)	Rue Du Gaillard 5
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gembloux, Namur, 5030 Belgium	Medical Device Contract 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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Validation of processes for production and service provision did not demonstrate the ability of the processes to achieve planned results consistently.

Specifically, the cleaning process for surgical instruments including vascular clamp products has not been validated:

Firm does not have a procedure for process validation.

Firm has prepared a plan for validation of cleaning process. The firm is validating the cleaning process described in work instruction Cleaning I-OPE-04. The work instruction describes pre cleaning if parts are "too dirty" in [redacted] (described as identical to [redacted] of cleaning process). Work instruction does not specify how long to pre treat and the validation plan R-DND-17-1 does not consider the pre treatment. Validation plan does not describe and define the [redacted]s from the [redacted] only the time and temperature. Procedure and validation plan do not describe how the [redacted] of the washing step will be controlled. Plan describes a process condition for [redacted] of the prepared cleaning agent but the work instruction does not specify how this is effected.

OBSERVATION 2

Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stephen D Eich, Investigator - Dedicated Device Cadre	X Stephen D Eich Investigator - Dedicated Device Cadre Signed By: Stephen D. Eich -S Date Signed: 03-19-2026 11:19:32	3/19/2026

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Specifically, Customer issued SCAR-2502 notifying SIBEL of non conformance on Debakey clamps, article number 30-0-2002-23-1, 33 pcs from lots [redacted] and [redacted] in stainless and steel. Customer found some cracks in the finger rings. Further inspection found other non conformance defect in the box lock. SIBEL opened Non Conformance/CAPA NOCO 2025-011 to address the issues of the SCAR.

There was no documented risk assessment for the box lock and finger ring cracks that were identified in the vascular clamp product.

NOCO 2025-011 identified a potential cause for cracks in finger rings that cracks in the finger rings may be due to the [redacted] at the supplier of the forging. There was no action documented to address the identified root cause. There was no documentation that the supplier was contacted to investigate the possible defect. NOCO 2025-011 included an action to modify the forging drawing to clarify the curve attribute of the box lock. An action identified that the new drawing would be provided to the supplier. There was no documentation of the notification of the supplier.

SCAR-2502 included a notification from NCMR-25-074 that 2002-23-6/BD3C1 had Buffing Compound in the box lock. NOCO 2025-011 did not include investigation of this SCAR finding.

OBSERVATION 3

Records of risk management activities in product realization were not adequately maintained.

Specifically, Vascular clamp product and/or Process Risk evaluations do not include the risk of cracks in vascular clamp product. Customer complaints have identified cracks in the box lock and finger rings of vascular clamps. Process Risk Analysis does not identify the risk if the passivation process is performed incorrectly or not made and does not evaluate the risk that the heat treatment process is not made or is

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incorrectly performed.

Potential Effects of failure in Process Risk Analysis R-DND-05-02 for Step Storage of Components, Step Selection of Components BOM, and Step Manufacturing Process and Controls for example include a description of Non conforming product/Reduced lifetime. There are no consideration of the risk to the patient or user to determine the severity. This includes for example Step storage of components with a failure mode of "The raw material, semi-finished product and [redacted]" and the potential effect is Non conform product/Reduced lifetime.

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

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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."