DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	6/8/2026-6/10/2026
	FEI NUMBER 3017923561

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ninad R. Daftari, COO

FIRM NAME	STREET ADDRESS
Saris and Things, Inc.	24119 W Riverwalk Ct Unit 131
CITY, STATE, ZIP CODE, COUNTRY Plainfield, IL 60544-8110	TYPE ESTABLISHMENT INSPECTED Repackager/Relabler

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

The quality management system was not documented and effectiveness was not maintained in accordance with applicable regulatory requirements.

Specifically, your firm is a (b) (4) of the (b) (4), which includes the (b) (4) and (b) (4) cleared under (b) (4), product code (b) (4) (b) (4) is intended to be used to (b) (4) patient's (b) (4) to (b) (4) for (b) (4), and (b) (4). Your firm has distributed a total of (b) (4) units since start of manufacturing in 2024. Your firm's quality management system has not been documented and maintained for effectiveness in accordance with the applicable regulatory requirements as followed:

A. Your firm failed to document and maintain risk management documentation required for planning product realization. Your firm has not documented or maintained a risk management procedure, risk management plan, hazard analysis nor failure mode and effects analysis.

B. Your firm failed to document and maintain the validation of software used to manage patient assignments and (b) (4) distribution. Additionally, your firm does not maintain a software validation procedure. Your firm developed the software to be customized to your operations and failed to complete software validation to validate the intended use of the software prior to the distribution of finished product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shuana H Xiong, Investigator	X Shuana H Xiong Investigator Signed By: Shuana H. Xiong -S Date Signed: 06-10-2026 14:27:46	6/10/2026

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C. Your firm failed to document and maintain the approval and monitoring of suppliers to ensure purchased product meets the required specifications and is proportionate to the risk associated with the finished medical device. Additionally, your firm failed to evaluate and document the approval and monitoring of suppliers and the receipt and acceptance of purchased product from suppliers to verify the purchased product is proportionate to the risks associated with the product.

D. Your firm failed to document and maintain a medical device file for each medical device type or family that contains, or references documents generated to demonstrate conformity to the requirements of the international standard and compliance with applicable regulatory requirements such as description, required specifications and procedures for measuring and monitoring.

E. Your firm failed to document and maintain the control of production for the (b) (4) of the manufactured finished (b) (4). Your firm requires each lot and batch that is manufactured to be documented on Form-001, the Batch Build Record; however, your firm failed to document any production of batches on Form-001.

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	Shuana H Xiong, Investigator X Shuana H Xiong Investigator Signed By: Shuana H. Xiong -S Date Signed: 06-10-2026 14:27:46	6/10/2026

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Annotations to Observations

Observation 1: Promised to correct

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	Shuana H Xiong, Investigator X Shuana H Xiong Investigator Signed By: Shuana H. Xiong -S Date Signed: 06-10-2026 14:27:46	6/10/2026

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."