DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	7/1/2026-7/2/2026
	FEI NUMBER 1222168

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hanbin Suh, Chief Operations Officer

FIRM NAME	STREET ADDRESS
Shent USA, Inc.	44 Bearfoot Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Northborough, MA 01532	Medical Device

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

Design and development outputs did not meet the input requirements for design and development and provide appropriate information for purchasing, production, and service provision.

Specifically,

A) Product Specification (b) (4), dated 02/02/2026, identifies component materials of the Sclerotherapy Needle, Class II medical device, as: injection needle (b) (4) Stainless Steel"; catheter shaft (b) (4) handle/locking cap/luer (b) (4) In each case, (b) (4) distinct materials or alloys are listed as alternatives without designating which is required. (b) (4) and (b) (4) are distinct stainless-steel alloys; (b) (4) are fundamentally different polymers; and (b) (4) have different mechanical profiles. Across all three components, no material grade, temper, or condition, or referenced material standard is defined. No verifiable acceptance criteria exist for the locking cap - for example, force requirements. No material standard is referenced for any component, and it cannot be determined from the specification which specific materials were evaluated for biocompatibility, such that a substitution would trigger re-evaluation. (b) (4) bears no approval signature by your firm.

B) The predecessor product specification, (b) (4), dated June 2016, which governed the Sclerotherapy Needle prior to (b) (4), similarly does not define material specifications for any

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey J Thibodeau, Investigator	X Jeffrey J Thibodeau Investigator Signed By: JEFFREY J. THIBODEAU -S Date Signed: 07-02-2026 14:33:22	7/2/2026

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FIRM NAME Shent USA, Inc.	STREET ADDRESS 44 Bearfoot Road
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component.

C)The sterile barrier system packaging materials are not defined in (b) (4) dated 02/02/2026, unsigned DMR-022 dated 01/30/2026, or predecessor product specification (b) (4) dated June 2016. None of these documents specify the pouch material construction, material grade, supplier specifications, or acceptance criteria for the sterile barrier system.

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jeffrey J Thibodeau, Investigator X Jeffrey J Thibodeau Investigator Signed By: JEFFREY J. THIBODEAU -S Date Signed: 07-02-2026 14:33:22	7/2/2026

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."