**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510)337-6700 Fax:(510)337-6702 | 6/1/2026-6/5/2026<br>FEI NUMBER<br>3012448339 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lawrence S. Nichols, CEO

| FIRM NAME | STREET ADDRESS |
|---|---|
| Smart World LLC | 48225 Lakeview Blvd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Fremont, CA 94538-6519 | Contract Sterilizer |

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 WE OBSERVED:**

## OBSERVATION 1

Requirements related to product do not include requirements necessary for specified or intended use, as known.

Specifically,

Your firm performs (b) (4) sterilization contract services for medical devices. WI-43, (b) (4), defines (b) (4) as "(b) (4) run Performance Qualification, measurement of (b) (4) and (b) (4) in material (b) (4) under defined conditions." SOP-16, (b) (4) Guidelines, indicates that (b) (4) "is a requirement before Steri-Tek can issue a Certificate of (b) (4) when processing product, guaranteeing a (b) (4)." Your firm's management confirmed that one of the key outputs of a (b) (4) is the Product Process Specification (PPS), which is the primary record that documents the requirements related to product. Additional critical parameters are documented in your firm's (b) (4) report.

Your firm performed (b) (4), a (b) (4) process validation, on the (b) (4) System for one of your customers. According to your protocol, this study was performed to characterize the (b) (4) Your firm's management confirmed that the (b) (4) Report (dated 3/8/2023) documents the specifications for the (b) (4) process cycle. This (b) (4) report for (b) (4) states that product (b) (4) requirements will be met during routine (b) (4) when processed per the PPS established by this (b) (4). This (b) (4) report states "Relevant customer information, handling instructions and processing instructions necessary for

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(b) (4) the device are documented in Table 1a and Table 1b." Table 1a indicates that the part numbers are (b) (4) and (b) (4) Additionally, the scope section of the (b) (4) Protocol for the (b) (4) System indicates that part numbers (b) (4) and (b) (4) are in scope of the study. While your firm's CEO confirmed verbally that it is critical that only product included in the validated processing family is sterilized per (b) (4), the PPS fails to include a requirement to ensure that only validated part numbers are processed in the (b) (4) cycle.

SOP-18, Receiving and Processing Order Acceptance (dated 2/4/26) describes the QA Check process under section 4.9.1.1, which states that Quality will verify that incoming product information matches the PPS. Additionally, your firm's quality agreement with your customer indicates in Attachment C "Each shipment of Products for processing will be accompanied by a document such as the Steri-Tek Service Order Form or Customer's packing list, manifest, or bill of lading stating the number of pallets, cartons, packages, or other designated units, as appropriate, listed by Customer's part number, lot number, and sterilization lot number, and indicating the non-sterile nature of the shipped Products." However, the PPS does not specify to verify the part numbers on the Service Order Form (SOF) received from the customer to ensure that only validated part numbers are processed, and your firm management confirmed that this is not done.

SOP-15, Risk Management, states that "All steps in the (b) (4) process will be evaluated for potential risks that would lead to processing product outside the required specifications." MISC-16, Risk Assessment, documents the following risk, "Incorrect product or product amount is received". The corresponding process step is "Product is received at Steri-Tek". The documented risk control is "Product counted, inspected and compared to SOF information." SOP-15 states that all steps in the (b) (4) process will be evaluated, which includes the process step of product being received at Steri-Tek. However, your firm is not following your own procedure, since your PPS for (b) (4) only requires for the (b) (4) to be checked. Your firm's management stated that including the correct products in the (b) (4) report is the customer's responsibility.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br>Jordan I Abel, Investigator<br>Sasha L Eckstein, Investigator | DATE ISSUED<br>6/5/2026 |
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X Jordan I Abel Investigator Signed By: 2004376737 Date Signed: 06-05-2026 16:32:39

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Your firm has completed (b) (4) jobs for processing of the (b) (4) System under (b) (4) Although the (b) (4) of (b) (4) only indicates that the scope includes part numbers (b) (4) and (b) (4), zero of the (b) (4) jobs were completed for (b) (4) or (b) (4). For example, Job (b) (4) , all reference (b) (4) and/or (b) (4)

**OBSERVATION 2**

One or more processes for risk management in product realization have not been adequately documented.

Specifically,

SOP-15, Risk Management defines risk as "combination of the probability of occurrence of harm and the severity of that harm." Additionally, section 4.2.1 states, "the severity of identified risks shall be determined based on a combination of the occurrence of the potential failure and the ease of occurrence." However, SOP-15 calculates risk level using frequency of occurrence and ease of occurrence, with no documented justification for how ease of occurrence is representative of, or a valid substitute for, severity of harm to the patient. As a result, severity of harm is not considered when determining risk levels (e.g., (b) (4) These risk levels are used in your firm's risk assessment (MISC-16).

X Sasha L Eckstein
Investigator
Signed By: SASHA L. ECKSTEIN -S
Date Signed: 06-05-2026 16:33:08

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
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| | Jordan I Abel, Investigator<br>Sasha L Eckstein, Investigator | X Jordan I Abel<br>Investigator<br>Signed By: 2004376737<br>Date Signed: 06-05-2026 16:32:39 | 6/5/2026 |

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## Annotations to Observations

Observation 1: Under consideration

Observation 2: Promised to correct

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| **SEE REVERSE OF THIS PAGE** | EMPLOYEE(S) SIGNATURE<br>Jordan I Abel, Investigator<br>Sasha L Eckstein, Investigator | X Jordan I Abel<br>Investigator<br>Signed By: 2004376737<br>Date Signed: 06-05-2026<br>16:32:39 | DATE ISSUED<br>6/5/2026 |

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."