DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	10/15/2018-10/25/2018* FEI NUMBER 3002695476

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kevin J. Seifert, President & CEO

FIRM NAME	STREET ADDRESS
Nurse Assist, LLC	4409 Haltom Rd
CITY, STATE, ZIP CODE, COUNTRY Haltom City, TX 76117-1207	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, your firm's Corrective and Preventive Action procedure does not include all the requirements of identifying the actions needed to correct and prevent recurrence of nonconforming product. In addition, your firm did not establish the requirements for verifying and validating the corrective and preventive action to ensure that such actions are effective. For example, your firm has initiated and closed the following CAPAs to prevent the microbial contamination at your sterile water/ saline manufacturing facility since 2017:

CAPA No.	Date Initiated	Description	Status
287	06/02/2017	High bioburden in filling line hoses	Closed 07/05/2017
289	06/07/2017	Lab OOS – Bioburden testing	Closed 09/01/2017
292*	07/10/2017	Bioburden results above action level	Closed 03/07/2018 *Re-opened 08/07/2018
293	07/10/2017	Bioburden results above action level	Closed 03/07/2018

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EMPLOYEE(S) SIGNATURE
Roy Baby, Investigator

X Roy Baby Investigator Signed By: 2000351084 Date Signed: 10-25-2018 10:09:41

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Your firm continues to have bioburden results above action levels in the fluid lines. Your firm has initiated at least 32 nonconformances due to bioburden issues since 07/10/2017, primarily in the bottle and cup filling lines.

OBSERVATION 2

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, your firm has not validated the effect of (b) (4) sterilization for your sterile water/ saline bottles. Your firm's Vice President of Operations stated that all bottles that are (b) (4) are then packaged in tracheostomy care kits with the water/ saline bottles, and are (b) (4). Your firm did not validate the (b) (4) sterilization process with a high degree of assurance and according to established procedures.

OBSERVATION 3

Procedures to prevent contamination of equipment or product by substances that may have an adverse effect on product quality have not been adequately established.

Specifically, your firm has not taken all precautions to prevent contamination of equipment or product by substances that may have an adverse effect on product quality.

For example, on 10/15/2018 and 10/16/2018, I observed the following in the sterile fluid manufacturing facility:

- Leaking (b) (4) filter in the (b) (4) system which is used for manufacturing USP sterile water and normal saline.
- Rusty metal support above the saline mixing tanks with (b) (4). The opening for the (b) (4) was not closed properly

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- Dripping fluids in the bottle filling lines
- Cup line support structure observed to be soiled with debris
- Three stained ceiling tiles above the (b) (4) system
- Employee practices such as reusing the gloves that fell on the floor, unclean gowns, overreaching the open filled cups with water to put the closure lid in the cup line

Your firm has not taken adequate measures to prevent contamination that may have an adverse effect on product quality until 10/16/2018.

OBSERVATION 4

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically, your firm did not establish procedures addressing identification, documentation, evaluation, segregation, and disposition of nonconforming products in production. Your firm did not document nonconformance or quantities of nonconforming products identified during manufacture. Your firm scraped the nonconforming products without conducting any evaluations and/ or implementing corrective or preventive actions.

For example, on 10/15/2018 and 10/16/2018, numerous counts of nonconforming products were observed to be discarded in the syringe line, cup line and the bottle line. Your firm did not document in-process nonconformance or quantities of nonconforming products in the device history record.

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OBSERVATION 5

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically, your firm's "Supplier Assessment" procedure, QP010, does not ensure that the evaluation and selection of potential suppliers and consultants are based on their ability to meet specified requirement, including quality requirements.

- Your firm does not have a Supplier Assessment Report, Form F-024, for your Level 1 (high risk) supplier of syringes.
- Your designated consulting firm, (b) (4), who performs the management of the Quality System, does not appear on your approved supplier list.
- Your firm did not review and classify all your suppliers in accordance with your procedure. For example, (b) (4) system servicing provider as well the calibration service providers are classified as Level III, requiring no evaluation.

OBSERVATION 6

Software used as part of production and the quality system has not been adequately validated for its intended use according to an established protocol.

Specifically, your firm did not have any documentation to support the software validation activities and the results for the computer data processing systems used in production and quality systems.

For example, your firm did not have any documentation to demonstrate that (b) (4) software was validated for its intended use in production or the quality system. Your firm has installed and has been utilizing the software for

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over 10 years in production order processing, inventory management, accounting, sales, as well as in generating bill of materials for production orders.

In addition, your firm did not have any documentation to demonstrate that the (b) (4) spreadsheet software used to log and update complaints, nonconformance, CAPA, lab results, maintenance records and other documents was validated for its intended use in the quality system. Your firm has not validated that the software can prevent unauthorized changes from being made to the data.

***DATES OF INSPECTION**

10/15/2018(Mon), 10/16/2018(Tue), 10/18/2018(Thu), 10/19/2018(Fri), 10/23/2018(Tue), 10/25/2018(Thu)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

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