DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	06/08/2010 - 06/10/2010
	FEI NUMBER 3004905773

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Connie (NMI) Shannon, Owner/Secretary Treasurer

FIRM NAME	STREET ADDRESS
Care Tech Industries, Inc.	8976 Seminole Blvd.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seminole, FL 33772	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

The quality policy, quality objectives, and were not established by management with executive responsibility.

Specifically, management with exectuive responsibility has not established a quality policy or quality objectives at the firm to ensure the Odatus II, Odatus IV, Odatus 16, Odatus European, Odatus HAZMAT, Odatus Immune System, or Odatus Defense System are designed and manufactured in accordance with Quality System Requirements. Further, management with executive responsibility has not established an organizational structure, established quality system procedures and instructions, or formally designated a Management Representative to establish and maintain quality system requirements to cover these devices.

OBSERVATION 2

Procedures for design control have not been established.

Specifically,

A. The firm has not established design control procedures for the Odatus II, Odatus IV, Odatus 16, Odatus European, Odatus HAZMAT, Odatus Immune System, or Odatus Defense System. More specifically, the firm has not established procedures to control any of the following design elements: design development activities, design inputs, design outputs, design review, design verification, design validation, design transfer, design changes.

B. The firm has not established a design history file (DHF) for these devices to demonstrate the manner in which the devices were designed and developed.

AMENDMENT 1

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	Joshua J. Silvestri, Investigator	06/10/2010

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C. The firm does not maintain records to show a Risk Analysis was performed as part of the design process and to demonstrate the device is safe and effective for its intended use and its intended environment, as evidenced by the following:

1. The firm does not maintain records of scientific evidence to demonstrate the (b) (4) byproduct, resultant from the Ozone synthesis accomplished by these devices, is produced at a level which is safe for humans and animals.

2. The firm does not maintain records of scientific evidence to demonstrate the levels of Ozone produced by these devices are safe when introduced to chemicals and materials commonly found in a household, such as carpet, cleaning products, and air fresheners.

3. These devices are designed to produce an accumulation of Ozone of up to 0.2 ppm by volume of air, which is in excess of the allowable limit for a medical device, as specified by regulation.

OBSERVATION 3

Procedures for acceptance activities have not been established.

Specifically, the firm has not established procedures for in-process or final acceptance testing to cover the Odatus II, Odatus IV, Odatus 16, Odatus European, Odatus HAZMAT, Odatus Immune System, or Odatus Defense System. Further, the firm does not maintain any records to demonstrate in-process or finished product testing have been performed to ensure the devices meet their intended design outputs, including demonstration that the intended quantity of Ozone is produced following adjustment of the number of steel plates installed in the unit and/or adjustment of the output setting on the device.

OBSERVATION 4

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

Specifically, the firm has not established a procedure for purchasing controls to verify that suppliers which provide components used to manufacture the Odatus II, Odatus IV, Odatus 16, Odatus European, Odatus HAZMAT, Odatus Immune System, or Odatus Defense System conform to specified requirements. Further, the firm does not maintain records to demonstrate they have evaluated their device component suppliers, and the firm has not established specifications requirements for incoming components.

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OBSERVATION 5

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically, the firm has not established procedures to cover receipt, review, and evaluation of complaints received for the Odatus II, Odatus IV, Odatus 16, Odatus European, Odatus HAZMAT, Odatus Immune System, or Odatus Defense System. Further, the firm received a complaint dated 11/17/2005 regarding nondisclosure of potential health affects their devices may have on persons with decreased lung function, and the firm does not maintain any records to demonstrate this complaint was addressed.

OBSERVATION 6

Procedures for quality audits have not been established.

Specifically, the firm has not established procedures for quality audits to cover the Odatus II, Odatus IV, Odatus 16, Odatus European, Odatus HAZMAT, Odatus Immune System, or Odatus Defense System. Further, the firm does not maintain any records to demonstrate internal quality audits have been conducted.

OBSERVATION 7

Procedures for corrective and preventive action have not been established.

OBSERVATION 8

Written MDR procedures have not been developed.

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Observation Annotations

Observations intentionally left blank.

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