DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	2/5/2019-2/6/2019
	FEI NUMBER 3005550381

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark E. Buchanan, President

FIRM NAME	STREET ADDRESS
Stetrix, Inc.	7531 Bartlett Corporate Cv E Ste 103
CITY, STATE, ZIP CODE, COUNTRY Bartlett, TN 38133-8951	TYPE ESTABLISHMENT INSPECTED Specification Developer

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 design input have not been adequately established.

Specifically,

Design input requirements that address the intended use of the Class II Hem-Avert® Perianal stabilizer were not adequately defined and documented. For example, the Design inputs for this device, (b) (4) (b) (4), do not address requirements for physical and performance characteristics, sterility, shelf life, labeling, or packaging. Furthermore, the design inputs were not reviewed and approved by a designated individual.

OBSERVATION 2

Procedures for design verification have not been adequately established.

Specifically,

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Mary A Millner, Investigator

X Mary A Millner
Investigator
Signed By: Mary A. Millner -S
Date Signed: 02-06-2019 15:16:12

DATE ISSUED
2/6/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	2/5/2019-2/6/2019 FEI NUMBER 3005550381

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark E. Buchanan, President	
FIRM NAME Stetrix, Inc.	STREET ADDRESS 7531 Bartlett Corporate Cv E Ste 103
CITY, STATE, ZIP CODE, COUNTRY Bartlett, TN 38133-8951	TYPE ESTABLISHMENT INSPECTED Specification Developer

The Design History File (DHF) for the Class II Hem-Avert® Perianal Stabilizer does not contain adequate documentation of design verification to that confirm the design output meets the design input requirements. For example,

A. The DHF does not contain documentation that a verification study to confirm the design input of "(b) (4) " was conducted.

B. The test report (b) (4) , approved 11/7/2008, documents the results of a (b) (4) that was conducted to determine whether the (b) (4) (b) (4) process affects the material characteristics of the plastic wedge of the Hem-Avert® Perianal Stabilizer. During this inspection you were unable to demonstrate acceptance criteria was established for this verification study.

OBSERVATION 3

Procedures for design validation have not been adequately established.

Specifically,

A. The design validation of the Hem-Avert® Peri-Anal Stabilizer included (b) (4) during which (b) (4) . During this inspection you were unable to demonstrate acceptance criteria were established prior to the performance of the validation study. Furthermore, the results of the (b) (4) study, including the (b) (4) (b) (4) were not documented in the design history file (DHF).

B. The Risk Assessment – dFMEA for the Hem-Avert® Peri-Anal Stabilizer is incomplete. Potential risks associated with the sterility of the device and potential risks associated with the new indication for use of reducing the occurrence of caesarean delivery were not evaluated.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Mary A Millner, Investigator	X Mary A Millner Investigator Signed By: Mary A. Millner -S Date Signed: 02-06-2019 15:16:12	2/6/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	2/5/2019-2/6/2019
	FEI NUMBER 3005550381

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark E. Buchanan, President	
FIRM NAME Stetrix, Inc.	STREET ADDRESS 7531 Bartlett Corporate Cv E Ste 103
CITY, STATE, ZIP CODE, COUNTRY Bartlett, TN 38133-8951	TYPE ESTABLISHMENT INSPECTED Specification Developer

OBSERVATION 4

Procedures for identifying product during all stages of receipt, production, distribution, and installation have not been established.

Specifically,

You have not established procedures to ensure product that has not been received into inventory is adequately identified. For example, during this inspection product that was awaiting incoming inspection was observed on a shelf next to received product. There was no sign, tag, or other identifier to indicate the product was awaiting incoming inspection and had not been received into inventory.

OBSERVATION 5

Quality audits have not been performed.

Specifically,

During this inspection you were unable to find documentation that an internal quality audit has been conducted at this facility per the requirements of your procedure Internal Quality Audit (SI-IQZ-001, Rev. B).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Mary A Millner, Investigator	X Mary A Millner Investigator Signed By: Mary A. Millner -S Date Signed: 02-06-2019 15:16:12	2/6/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	2/5/2019-2/6/2019
	FEI NUMBER 3005550381

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark E. Buchanan, President	
FIRM NAME Stetrix, Inc.	STREET ADDRESS 7531 Bartlett Corporate Cv E Ste 103
CITY, STATE, ZIP CODE, COUNTRY Bartlett, TN 38133-8951	TYPE ESTABLISHMENT INSPECTED Specification Developer

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Mary A Millner, Investigator	X Mary A Millner Investigator Signed By: Mary A. Millner -S Date Signed: 02-06-2019 15:16:12	2/6/2019