DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	12/5/2022-12/8/2022 FEI NUMBER 3000296634

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Haithem Boukhari, CEO	
FIRM NAME Prince Medical S.A.S.	STREET ADDRESS 64 Rue Gutenberg, ZA la Sente du Moulin
CITY, STATE, ZIP CODE, COUNTRY Ercuis, Oise, 60530 France	TYPE ESTABLISHMENT INSPECTED 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 receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically, the current complaint handling procedure, *Gestion Des Reclamations Clients* (Customer Claims Management), No.5130, Index 001, dated 9/8/2022, and the previous complaint handling procedure in *Management of Non-Conformities*, No.5112, Index 006, dated 9/13/2019, are inadequate and have not been established in that:

A. Complaints are not evaluated for FDA Medical Device Reporting requirements. 11 of 12 complaints reviewed lack a documented evaluation to determine whether the complaint represents an event which is required to be reported to FDA under Medical Device Reporting requirements. Examples include complaint numbers 22R039, 22R038, 22R035, 22R033, 22R025, 22R020, 22R016, 22R014, 21R018, 21R012, and 21R007 regarding malfunctions for the Gastric Balloon Retraction Kit (aspiration needle and retractor). Furthermore, complaint procedures No.5130 and No.5112 do not require an evaluation of complaints for Medical Device Reporting requirements.

B. Complaints are not evaluated to determine whether an investigation is necessary. Five (5) of 12 complaints reviewed were not evaluated to determine whether an investigation was necessary and

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lack documentation of the reason no investigation was made and the name of the individual responsible for the decision to not investigate. Examples include complaint numbers 22R038, 22R035, 22R025, 22R020, and 21R007 regarding the Gastric Balloon Retraction Kit (aspiration needle and retractor). Furthermore, complaint procedures No.5130 and No.5112 require complaint investigations, but do not require documentation of the reason when no investigation is made.

C. Complaints are not processed in a uniform and timely manner. Among complaints currently open, four (4) of six (6) complaints reviewed have been open for several months and have no documented complaint investigation and no documented evaluation for Medical Device Reporting requirements. Examples include complaint numbers 22R038, 22R035, 22R025, and 22R020 for the Gastric Balloon Retraction Kit (aspiration needle and retractor). Additionally, no complaint form was opened for complaint number 22R025, received via email on 7/28/2022, which reported a prong of the Gastric Balloon Retraction Kit (b)(4) pierced through the catheter and was unable to be advanced outside of the catheter to grasp and remove a gastric balloon. Furthermore, complaint procedures No.5130 and No.5112 do not establish time frames for completing complaint handling stages or time frames evaluating Medical Device Reporting requirements.

D. Complaint records inconsistently include the address and/or phone number of the complainant. Complaint procedure No.5130 only requires specifying the "contact details" of the complainant and previous procedure No.5112 did not require documentation of contact information.

This is a repeat observation from the previous FDA inspection dated 3/28/2012.

OBSERVATION 2

The design verification results, including identification of the design, method(s), the date and the individual(s) performing the verification, were not documented in the design history file.

Specifically, the design history file (DHF) for the Echo-Hood Aperture echo-endoscope balloon [redacted]

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[(b)(4)] does not contain design verification (i.e., protocol or report) to confirm that design outputs meets design input requirements. Additionally, the DHF does not contain functional performance specifications for the device as only dimensional specifications are defined.

OBSERVATION 3

Requirements that must be met by contractors and consultants have not been established.

Specifically, the current procedure *Selection et Evaluation des Fournisseurs* (Selection and Evaluation of Suppliers), No.5111, Index 005, dated 10/10/2022, and previous version *Evaluation, Selection, Surveillance et Reevaluation des Fournisseurs*, No.5111, Index 004, dated 3/22/2021, have not be established in that:

A. There is no procedure or work instruction to complete form #5122/A *Supplier or subcontractor non-conformity*, which is used to initiate a supplier's investigation and corrective action in response to a product defect. Additionally, #5122/A forms issued to the supplier of the Echo-Hood Aperture echo-endoscope balloon [(b)(4)] and the Gastric Balloon Extraction Kit [(b)(4)] are incomplete. For example, a #5122/A form was opened on 10/28/2021 under #21NCF011 for two defects regarding catheter tapering. The "SUPPLIER PART" section of the form is incomplete.

B. The required form for supplier evaluation, #5111A *Supplier Questionnaire*, was not completed for the critical supplier of the latex raw material used to manufacture the Echo-Hood Aperture echo-endoscope balloon [(b)(4)]

C. Change notification agreements are not in place with four (4) critical suppliers of raw materials or components used to manufacture the Echo-Hood Aperture echo-endoscope balloon [(b)(4)] and the Gastric Balloon Extraction Kit [(b)(4)]

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OBSERVATION 4

Procedures for corrective and preventive action have not been established.

Specifically, the current procedure *Gestion des Action Correctives et Preventives* (Management of Corrective and Preventive Actions), No.5123, Index 006, dated 9/7/2022, and previous version *Action Corrective, Preventive et D'amelioration*, No.5123, Index 005, dated 10/15/2020, have not been established in that required effectiveness verifications were not completed for CAPA numbers 21AC006 and 21AC007. No effectiveness verification was conducted after action implementation, there is no documented verification plan, and both CAPAs remain open.

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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

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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."