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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768 | 6/15/2017-6/16/2017 |
| | FEI NUMBER<br>3005878604 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

James A. Magnuson , Vice President

| FIRM NAME | STREET ADDRESS |
|---|---|
| Healthline Medical Products, Inc. | 1065 E Story Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Winter Garden, FL 34787-3732 | 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,

A. Corrective and Preventive Action procedure, QAP/0600-R, Rev 0, does not define requirements to investigate existing and potential quality problems in order to identify the underlying cause for such problems. Further, you did not fully investigate the problems under Complaint #41, regarding a device damaged during shipment, in order to determine if the work instructions for the packaging operation were adequate to ensure control over the process. This written procedure currently does not include instruction to use inert packaging material, and your corrective action for Complaint #41 included training on use of inert packaging material but did not include revision of the written procedure.

B. You have not fully implemented the Corrective and Preventive Action procedure, QAP/0600-R, Rev 0. For example,

i. You did not evaluate and approve the corrective actions taken under your response to Complaint #41, involving a shower chair device that was determined to have been damaged during shipment, which included instructing employees on using the proper amount of inert packaging material and included developing a new package insert to caution users to inspect devices for damage upon receipt.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Joshua J Silvestri, Investigator<br>6/16/2017<br>X Joshua J Silvestri<br>Joshua J Silvestri<br>Investigator<br>Signed by: Joshua J. Silvestri -S | 6/16/2017 |

ii. You did not verify or validate the effectiveness of your corrective actions taken under Complaint #41. You did not evaluate the modifications to the amount of inert packaging material used, and you did not validate the new package insert, and you did not evaluate the effect of these actions in order to show they prevent the quality problem from recurring.

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**OBSERVATION 2**
Corrective and preventive action activities and/or results have not been adequately documented.

Specifically, you do not have training records covering the corrective actions taken under Complaint #41, to include training on the modification of the use of inert packaging and training on the modification of the device master record for inclusion of a new package insert.

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**OBSERVATION 3**
Records of complaint investigations do not include required information.

Specifically, your complaint records do not consistently include all pertinent details of the complaint and/or investigation. For example,

A. Your records for Complaint #41, dated 06/02/2017, do not include the information and details collected to determine that the damage to the device was caused during shipment, such as whether or not the customer ever used or attempted to use the device prior to discovering the damage.

B. Your records for Complaint #30, dated 12/21/2015, do not list your attempts to identify the manufacturing code of the subject device. Further, the records do not list any evaluation of your complaint data to determine the rate at which similar complaints had been received, although this is required by your current Customer/Client Complaint Handling Procedure, QAP/0500, Rev 1.

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## OBSERVATION 4

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

Specifically, you do not have written procedures defining evaluation of service providers and contractors. Further, you have no documented evaluation of the companies you utilize to ship your finished devices, and you have complaints regarding devices damaged during shipment.

## OBSERVATION 5

The evaluation of potential suppliers was not documented.

Specifically, you did not document the evaluations of your supplier for PVC pipe and supplier for castors in order to demonstrate these suppliers were evaluated at the rate of at least every (b) (4) , as required by your current written procedure: General Purchasing, PUR/0100, Rev 2. You evaluated each of these suppliers during 2013, 2014, and 2016 but did not document any of these evaluations.

## OBSERVATION 6

The device history record does not demonstrate that the device was manufactured in accordance with.

Specifically, your device history records do not include or refer to all device labeling. For example, the records do not include or refer to the package insert that covers, in part, cleaning instructions and do not include or refer to the package insert that covers inspection of the device for damage that may have been caused during shipment.

## Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated

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Observation 3: Not annotated
Observation 4: Not annotated
Observation 5: Not annotated
Observation 6: Not annotated

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