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	11/03/2008 - 11/07/2008* FEI NUMBER 3005878604

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Travis G. Magnuson, General Manager

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

OBSERVATION 1

The procedures for implementing corrective and preventive actions were not complete and implemented.

Specifically, Healthline Medical Products failed to implement a corrective action regarding Complaint #2, received by Healthline Medical Products on 04/15/2008, involving the failure of the Shower Commode Chair, Model #SC6014X. The "Assembly Guide for the Healthline Commode Shower Chair" is inadequate to assemble the device in accordance with its design and Healthline Medical Products' manufacturing assembly instruction for the device. No corrective action has been implemented by Healthline Medical Products to correct the assembly guide provided to the end user with the shipment of the device.

Further, Healthline Medical Products' procedure, QAP/0600-R, Corrective and Preventive Action, Issue 1, Rev. 0 (01/01/2008), for implementing corrective and preventive actions for manufactured devices including Shower Gurneys, Model Nos. ABSG200W5 and TSG100W5, does not contain provisions including:

i. The analysis of sources of quality data by means of appropriate statistical methodology to identify existing and potential causes of nonconforming product or other quality problems;
ii. Investigating causes of non-conformities related to product, processes, and the quality system;
iii. Verifying or validating corrective and preventative actions and ensuring that the actions are effective and do not adversely affect the finished device, process, and/or quality system; and
iv. The implementation and recording of changes in methods and procedures needed to correct and prevent identified problems.

This is a continued observation as documented in Form FDA 483, Inspectional Observations, Observation 8 & 9, issued to the firm on 02/15/2007 and Observation 6, issued to the firm on 11/09/2007.

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	Salvatore N Randazzo, Investigator Joshua J. Silvestri, Investigator	11/07/2008

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OBSERVATION 2

Complaint handling procedures for receiving, reviewing, and evaluating complaints have not been implemented.

Specifically, Healthline Medical Products has not fully implemented procedure, QAP/0500, Customer/Client Complaint Handling Procedure, Issue 1, Rev. 0 (01/01/2008), Section 5.3.11 and 5.3.12 in that, complaints involving the possible failure of a device to meet any of its specifications were not adequately investigated where necessary including:

i. Complaint #1 (received by Healthline Medical Products on 03/13/2008) involving a loose joint on a Shower Chair, Model #SC6013S. Healthline investigation failed to determine the possible root-cause of the loose joint (i.e.: [redacted] process, etc.), but instead concluded the malfunction would result in "no real safety issue that would cause harm". Complaint #1 does not document any follow-up to the customer regarding Healthline Medical Products' investigational findings.

(b)(4)

ii. Complaint #2 (received by Healthline Medical Products on 04/15/2008) involving the failure of [redacted] and connector on a Shower Commode Chair, Model #SC6014X. Healthline investigation failed to determine the possible root-cause of the [redacted] and connector failure (i.e.: assembly instructions provided to user, etc.), but instead concluded "There is no way that the joints shown in the picture could have cracked the way they did without mis-use of chair." Complaint #2 does not document any follow-up to the customer regarding Healthline Medical Products' investigational findings.

(b)(4)

iii. Complaint #3 (received by Healthline Medical Products on 08/28/2008) involving a cracked seat, Vacseat 18". Healthline investigation failed to determine the possible root-cause of the cracked seat (i.e.: purchasing, manufacturer's assembly, etc.), but instead concluded "Only possible way for the seat to crack in the corner would be that it cracked at the time they (user) put the seat back on after cleaning." Complaint #3 does not document any follow-up to the customer regarding Healthline Medical Products' investigational findings.

This is a continued observation as documented in Form FDA 483, Inspectional Observations, Observation 4, issued to the firm on 02/15/2007 and Observation 7, issued to the firm on 11/09/2007.

OBSERVATION 3

Procedures to control the design process of the device were not implemented.

Specifically, Healthline Medical Products has not implemented design control procedures, DES/0100, Design and Project Development Plan, Issue 1, Rev. 0 (01/01/2008), to control the design of manufactured devices including Shower Gurneys, Model Nos. ABSG200W5 and TSG100W5, which are currently manufactured by Healthline Medical Products.

This is a continued observation as documented in Form FDA 483, Inspectional Observations, Observation 12, issued to the firm on 02/15/2007 and Observation 3, issued to the firm on 11/09/2007.

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OBSERVATION 4

Process control procedures that describe any process controls necessary to ensure conformance to specifications were not defined and implemented.

Specifically,

i. Healthline Medical Products' procedure QCP/0200, Receiving, In-Process & Final Verification Procedures, Issue 1, Rev. 0 (01/01/2008), neither has defined provisions to perform verification of information provided to the firm through vendor surveys, nor has it defined and implemented provisions for Healthline Medical Products to conduct testing to verify required specifications are met for incoming components, such as [redacted] and [redacted] used in the manufacture of devices including Shower Gurneys, Model Nos. ABSG200W5 and TSG100W5. (b)(4)

ii. Healthline Medical Products' "Procedure for Cutting Pipe" (01/18/2008) and "Builders Instructions List for MDR" are not fully implemented and provide conflicting sets of instructions. The pipe cutting procedure states, at step 3, to cut pipes that is intended to be used for a specific device build ; however, the build procedure states, in step 2, that [redacted] used to build the devices are obtained from various bins containing pre-cut pipe of various lengths. An employee building a device was observed pulling multiple pieces of pipe from an area outside the medical device manufacturing area in a manner not consistent with either of the above mentioned procedures. (b)(4)

iii. Healthline Medical Products' "Procedure for Cutting Pipe" (01/18/2008) is not fully implemented. Step 5 of the procedure instructs to always measure every pipe before assembly to ensure the cutting process; however, there is no documentation to show completion of this step.

OBSERVATION 5

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements were not complete and implemented.

Specifically, Healthline Medical Products' purchasing control procedure, PUR/0100, General Purchasing, Issue 1, Rev. 0 (01/01/2008) is not complete and has not been implemented to ensure that all purchased or otherwise received raw material components including [redacted] conform to specified requirements for use in the manufacture of devices including Shower Gurneys, Model Nos. ABSG200W5 and TSG100W5. Healthline Medical Products' procedure, PUR/0100, states all supplier/vendors are qualified as approved vendors in accordance with procedure PUR/0200, Vendor Assessment Procedure, and then placed on the Healthline Medical Products' "Official Vendor List" as appropriate. Healthline Medical Products' Vendor Assessment Procedure, PUR/0200 is not approved and implemented for use and the Vendor Survey Checklist, PUR/0200-3, currently used by Healthline Medical Products for qualification of vendors is not defined in PUR/0100. Further, the results of Healthline Medical Products' Vendor Survey Checklist are not verified as accurate by Healthline Medical Products. (b)(4)

Healthline Medical Products has not ensured that the [redacted] process, as related to the strength of [redacted] has been (b)(4)

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appropriately validated by the [redacted] manufacturer/supplier. Healthline Medical Products continues to experience (b)(4) complaints involving the cracking/breaking of [redacted] used in the manufacture of Healthline Medical Products' devices.

This is a continued observation as documented in Form FDA 483, Inspectional Observations, Observation 7, issued to the firm on 02/15/2007 and Observation 5, issued to the firm on 11/09/2007.

OBSERVATION 6

Procedures have not been implemented to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality Systems regulation.

Specifically, Healthline Medical Products' "Builder Device History Record" (BDHR), Invoice #59819 demonstrates assembly activities were completed on 11/03/2008, and the BDHR is signed and dated on 11/03/2008 showing one device is built and approved; however, the device (unidentified on the BDHR) was not a completed finished-device as the BDHR indicates but was in-process and not fully built at the time the record was completed. This is not in accordance with Healthline Medical Products' procedure, QCP/0200, Receiving, In-Process & Final Verification Procedures, Issue 1, Rev. 0 (01/01/2008), Section 5.1.

This is a continued observation as documented in Form FDA 483, Inspectional Observations, Observation 2 (A), issued to the firm on 02/15/2007 and Observation 4, issued to the firm on 11/09/2007.

OBSERVATION 7

Quality audits were not conducted to verify that the quality system is effective in fulfilling your quality system objectives.

Specifically, Healthline Medical Products has not implemented procedure, QAP/0200, Internal Quality Audits, Issue 1, Rev. 0 (01/01/2008) for conducting quality audits. Healthline Medical Products has not conducted a quality audit, to date, of all required quality system criteria for manufactured devices including Shower Gurneys, Model Nos. ABSG200W5 and TSG100W5.

This is a continued observation as documented in Form FDA 483, Inspectional Observations, Observation 5 & 10, issued to the firm on 02/15/2007 and Observation 2, issued to the firm on 11/09/2007.

OBSERVATION 8

Management reviews were not conducted at defined intervals.

Specifically, Healthline Medical Products does not conduct management reviews in accordance with the Healthline Medical Products' procedure, QSM/01, Issue 1, Rev. 0 (01/01/2008). The procedure states management reviews are to be conducted "on an as needed basis, but no less than once per month". Healthline Medical Products has not conducted and documented management reviews for July 2008 and September 2008.

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This is a continued observation as documented in Form FDA 483, Inspectional Observations, Observation 11, issued to the firm on 02/15/2007 and Observation 1, issued to the firm on 11/09/2007.

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Observation Annotations

Observations intentionally left blank.

*** DATES OF INSPECTION:**
11/03/2008(Mon), 11/04/2008(Tue), 11/05/2008(Wed), 11/07/2008(Fri)

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