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	11/17/2009 - 11/19/2009
	FEI NUMBER 1000526376

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Ralph A. Milliken, President

FIRM NAME	STREET ADDRESS
Magnificent Medical Equipment, Inc. DBA Tony Riso Company	2641 NE 186th Ter
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Miami, FL 33180-2624	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 device history record does not include acceptance records that demonstrate the device is manufactured in accordance with the device master record.

Specifically, your firm fails to document
(a) incoming inspection of bare printed circuit boards from your supplier,
(b) inspection of populated printed circuit boards and
(c) final inspection of your medical devices.

*****This is a continued observation from previous FDA inspection dated 04/02-04/08.**

OBSERVATION 2

Production processes were not complete to ensure that a device conforms to its specifications.

Specifically, your firm fails to do (b)(4) testing of your medical devices.

*****This is a continued observation from previous FDA inspection dated 04/02-04/08.**

OBSERVATION 3

The device master record does not include or refer to the location of quality assurance procedures and specifications.

Specifically, your firm has no written procedures to cover
(a) incoming inspection of bare printed circuit boards and

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(b) final functional inspection of finished devices.

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OBSERVATION 4

Adequate quality requirements that must be met by contractors were not established.

Specifically, your firm has not assured that the contract manufacturers for your inserts and grips meet quality requirements and manufacture devices according to specifications.

OBSERVATION 5

Procedures to ensure that equipment is routinely calibrated were not established, documented, and implemented.

Specifically, your firm has failed to calibrate the equipment for example oscilloscopes and multimeters used in the testing of your medical devices.

***** This is a continued observation from previous FDA inspection dated 04/02-02/08.**

OBSERVATION 6

A process whose results cannot be fully verified by subsequent inspection and test has not been validated and approved according to established procedures.

Specifically, you firm provides partial recommended sterilization cycle for steam autoclave and chemical vapor methods in its labeling for inserts. Your firm has no sterilization validation of these recommended sterilization cycles to demonstrate sterility or to demonstrate recommended cycles will not adversely affect the material used in your inserts.

*****This is a continued observation from previous FDA inspection dated 04/02-04/08.**

OBSERVATION 7

Incoming product was not adequately inspected or tested to verify conformance to specifications.

Specifically, your firm received a shipment of O-Rings (b)(4) Black and (b)(4) Green) on 11/18/08 used in the manufacture of inserts. There is no documentation of testing or acceptance activities for these components.

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OBSERVATION 8

The procedures for implementing corrective and preventive actions were not established.

*****This is a continued observation from previous FDA inspection dated 04/02-04/08.**

OBSERVATION 9

Records of complaint investigations do not include the results of the investigation.

Specifically, your firm did not document thorough root causes and/or conclusion in the complaint sheet dated 06/02/09 06/16/09, 07/06/09 and 10/16/09.

*****This is a continued observation from previous FDA inspection dated 04/02-04/08.**

OBSERVATION 10

Corrective and preventive action activities have not been documented, including investigations of causes of nonconformities, the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, the verification or validation of corrective actions, and implementation of corrective and preventive actions.

*****This is a continued observation from previous FDA inspection dated 04/02-04/08.**

OBSERVATION 11

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

*****This is a continued observation from previous FDA inspection dated 04/02-04/08.**

OBSERVATION 12

Written MDR procedures have not been developed.

*****This is a continued observation from previous FDA inspection dated 04/02-04/08.**

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OBSERVATION 13

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

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OBSERVATION 14

Document control procedures were not established.

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Observation Annotations

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.	Observation 6:	Promised to correct.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.
Observation 9:	Promised to correct.	Observation 10:	Promised to correct.
Observation 11:	Promised to correct.	Observation 12:	Promised to correct.
Observation 13:	Promised to correct.	Observation 14:	Promised to correct.

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