



ETHYLENE OXIDE STERILIZERS



COMPLIANCE INSPECTION CHECKLIST

INSPECTION TYPE: ANNUAL (INS1, INS2) COMPLAINT/DISCOVERY (CI)
 RE-INSPECTION (FUI) ARMS COMPLAINT NO:

AIRS ID#: 0310379 **DATE:** 07/16/13 **ARRIVE:** _____ **DEPART:** _____

FACILITY NAME: MEDRONIC ENT

FACILITY LOCATION: 6743 SOUTHPOINT DR N
 JACKSONVILLE 32216-6218

OWNER/AUTHORIZED REPRESENTATIVE: EMMANUEL DUJARRIC **PHONE:** (904)332-8556
Email: _____ **Mobile:** _____

CONTACT NAME: KEVIN KRAUSE **PHONE:** (904)332-6707
Email: kevin.krause@medtronic.com **Mobile:** (904)382-0899

ENTITLEMENT PERIOD: 2/25/2011 / 2/25/2016
 (effective date) (end date)

PART I: INSPECTION COMPLIANCE STATUS (check only one box)

IN COMPLIANCE MINOR Non-COMPLIANCE SIGNIFICANT Non-COMPLIANCE

PART II: CONTROL TECHNOLOGY – Rule 62-213.300 FAC

Vent type(s) at the facility: Aeration Room-- Sterilization Chamber-- Chamber Exhaust--

Sterilization Chamber Vent

Has one of the following emission control devices been installed? Yes-- No--

If **yes**, indicate type below.

Acid-Water Scrubber----- Thermal Oxidation Unit--
 Catalytic Oxidation Unit-- Other-- _____
(Must submit information to DEP for approval)

Chamber Exhaust Vent

No emission control device. *(must use direct measurement in Part III)*
 Emissions manifolded to sterilization chamber vent control device.
 Dedicated emission control device (indicate type below).-----
 Acid-Water Scrubber----- Thermal Oxidation Unit--
 Catalytic Oxidation Unit-- Other -- _____
(Must submit information to DEP for approval)

PART III: MONITORING REQUIREMENTS – Rule 62-213.300 FAC

Has the facility conducted an initial performance test?
(Existing facilities by 6/8/98; new sources within 180 days after startup)----- Yes No

Acid-Water Scrubbers

What process parameter is the facility monitoring to determine compliance?
ethylene glycol concentration--- scrubber liquor tank level--

If the facility is monitoring the scrubber liquor tank level, has a liquid level indicator been installed?----- Yes No

Catalytic/Thermal Oxidation Units

Has the facility installed a temperature sensor that is accurate to within $\pm 10^\circ$ F?---- Yes No

Has the facility verified the accuracy of the temperature sensor?
(must be performed semiannually)----- Yes No

Direct Measurement

Has the facility installed a gas chromatograph?----- Yes No

PART IV: RECORDKEEPING REQUIREMENTS – Rule 62-213.300(3) FAC

Has the facility maintained the following records?

Owner's manuals, designs specifications, and other instructional materials for the sterilization unit and control equipment.----- Yes No

Records of ethylene oxide usage on a 12-month rolling average. ----- Yes No

Records of all initial performance tests, including control efficiency determinations. Yes No

Records of all temperature monitoring. (oxidation units only) ----- Yes No N/A

Records of all ethylene oxide concentration monitoring. (direct measurement only) Yes No N/A

Records of gas chromatograph calibration (direct measurement only) ----- Yes No N/A

Records of scrubber liquor level. (acid-water scrubbers only)----- Yes No N/A

Records of ethylene glycol concentration. (acid-water scrubbers only)----- Yes No N/A

David Herrera

7/16/13

Inspector's Name (Please Print)

Date of Inspection

2014

Inspector's Signature

Approximate Date of Next Inspection

COMMENTS: I met with Mr. Krause on 7/16/13 and the facility was in operation at the time of inspection. The new unit is in place and has been stack tested on 10/2/12, 10/3/12 and 10/4/12 and testing results have been submitted to the department. According to Mr. Krause the unit is still going through a rigorous process of 60 runs that will not be completed until sometime in August 2013. Then they have numerous reporting and requirements to put in place before they can officially put the new unit on-line. At this time, he is not sure when all this will be completed by. After a review of data, records and a walk through of the new unit and the existing unit, no violations to be noted at the time of inspection.