



ETHYLENE OXIDE STERILIZERS



COMPLIANCE INSPECTION CHECKLIST

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

AIRS ID#: 0310379 **DATE:** 5/27/2014 **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

Brenda Johnson

27 May 2014

Inspector's Name (Please Print)

Date of Inspection

2015

Inspector's Signature

Approximate Date of Next Inspection

COMMENTS: Facility was in operation at the time of inspection. I met with Mr. Krause and Debbie who operates the Sterilization Chambers. The New Sterilization Units were up and running properly. According to Mr. Krause the Old Sterilization Chamber is no longer being used but will be kept on site until all gas is used by December of 2014 and then they will take the unit out of service and dismantle the unit. They started using the New Sterilization Units officially in January of 2014. Records and logs were reviewed and no discrepancies or violations were noted at the time of inspection.