

30 September 2010

Mr. Leonard Sarapas  
Boston Scientific Corporation  
8 Industrial Drive  
Coventry, RI 02816

Dear Mr. Sarapas:

The Department of Environmental Management, Office of Air Resources has reviewed and approved your application for the installation of five aeration cells to be located at your 8 Industrial Drive, Coventry facility.

Enclosed is a minor source permit pursuant to our review of your application (Approval No. 2114).

The permit conditions and emission limitations in this permit also incorporate and include those in Approval No. 1280, 1394 & 1612 issued on 14 August 2001. Hereinafter the design, construction, and operation of all the equipment addressed in these approvals shall be subject to the permit conditions and emission limitations contained in this minor source permit.

If there are any questions concerning this permit, please contact me at 222-2808, extension 7028.

Sincerely,

Aleida M. Whitney  
Air Quality Specialist  
Office of Air Resources

cc: Coventry Building Official

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS  
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
OFFICE OF AIR RESOURCES

MINOR SOURCE PERMIT

*BOSTON SCIENTIFIC CORPORATION*

APPROVAL NOs. 1280, 1394, 1612 & 2114

Pursuant to the provisions of Air Pollution Control Regulation No. 9, this minor source permit is issued to:

*Boston Scientific Corporation.*

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**For the following:**

*Installation of five aeration cells (Approval No. 2114) for the ethylene oxide sterilization*

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*process and increase the allowable emissions of ethylene oxide. Add condition for*

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*annual allowable emissions. Remove condition B.4. Modify conditions A.2, B.5, C.2,*

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*D.2, E.1, E.3 and F.4*

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**Located at:** *8 Industrial Drive, Coventry*

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**This permit shall be effective from the date of its issuance and shall remain in effect until revoked by or surrendered to the Department. This permit does not relieve *Boston Scientific Corporation* from compliance with applicable state and federal air pollution control rules and regulations. The design, construction and operation of this equipment shall be subject to the attached permit conditions and emission limitations.**

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**Douglas McVay, Acting Chief  
Office of Air Resources**

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**Date of Issuance**

**STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS  
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
OFFICE OF AIR RESOURCES**

**BOSTON SCIENTIFIC CORPORATION**

**APPROVAL Nos. 1280, 1394, 1612 & XXXX**

Permit Conditions and Emission Limitations

A. Emission Limitations

1. Emissions of ethylene oxide from the sterilizer exhaust stream shall be treated by the Glygen 2000 scrubber (Approval No. 1394) and be reduced by 99.5% or greater before discharge to the Donaldson catalytic incinerator (Approval No. 1280).
2. Emissions of ethylene oxide from the sterilizer rear exhaust, sterilizer hoods, EtO gas storage room, the Glygen 2000 scrubber (Approval No. 1394) and the Lantec Q-Pac scrubber (Approval No. 1612) shall ultimately be routed to the Donaldson catalytic incinerator (Approval No. 1280) before discharge to the atmosphere. The Donaldson catalytic incinerator must reduce ethylene oxide emissions by 99.0% or greater, unless outlet emissions are below the greater of the lower limit of detection for the stack sampling method or 0.8 ppmv.
3. Emissions of ethylene oxide discharged from the aeration cells shall be treated by the Lantec Q-Pac scrubber (Approval No. 1612) and shall be reduced to a maximum concentration of 1 ppmv or by 99.9% or greater, whichever is less stringent, before discharge to the Donaldson catalytic incinerator (Approval No. 1280).
4. Emissions of ethylene oxide from the entire facility shall not exceed:
  - a. 15 lbs per day
  - b. 1298 lbs per year

B. Operating Requirements

1. The average daily usage of ethylene oxide at the facility shall not exceed 1,114.2 lbs (calendar month average).
2. The maximum daily usage of ethylene oxide at the facility shall not exceed 1,500 lbs.

3. The vacuum pump used to evacuate the sterilizer during the sterilization cycles shall be of a recirculating design.
4. The concentration of ethylene glycol in the scrubber liquor shall not exceed the maximum concentration determined as a site specific operating parameter during emission testing required under 40 CFR 63.363. Alternatively, the level of the scrubber liquor shall not exceed the maximum level determined as a site specific operating parameter during emission testing required under 40 CFR 63.363..
5. Whenever ethylene oxide is being discharged to the Donaldson catalytic incinerator the outlet temperature shall be maintained at or above 10°F below the baseline temperature determined as a site specific operating parameter during emission testing required under 40 CFR 63.363.
6. No more than seven sterilizers shall be discharged to the Glygen 2000 scrubber (Approval No. 1394) at any time.
7. No more than five aeration cells shall be discharged to the Lantec Q-Pac scrubber (Approval No. 1612) at any time.

C. Monitoring

1. The inlet and outlet gas temperature of the Donaldson catalytic incinerator shall be continuously monitored and recorded using a data acquisition system and temperature monitor that meets the requirements of 40 CFR 63.364(c).
2. The owner/operator shall, as determined in Condition D.2 of this minor source permit,:
  - a. Sample the scrubber liquor of each scrubber and analyze and record once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in 40 CFR 63.365(e)(1). Monitoring is required during a week only if the scrubber has been operated; or
  - b. Measure and record once per week the level of the scrubber liquor in the recirculation or treatment tanks. The owner or operator shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a sight glass, a marker on the tank wall, a dipstick, a magnetic indicator, etc.). Monitoring is required during a week only if the scrubber has been operated.

D. Emission Testing

1. Within 180 days of start up of the Lantec Q-Pac scrubber, emissions testing shall be conducted to demonstrate compliance with Condition A.3.
2. During the emissions test, the owner/operator shall establish as a site-specific operating parameter, either:
  - a. the maximum ethylene glycol concentration using the procedures described in 40 CFR 63.365(e)(1); or
  - b. the maximum liquor tank level using the procedures described in 40 CFR 63.365(e)(2).
3. Two copies of an emission testing protocol shall be submitted to the Office of Air Resources for review and approval at least 60 days prior to the performance of any compliance tests. The owner/operator shall provide the Office of Air Resources at least 60 days prior notice of any compliance test.
4. All test procedures used for compliance testing shall be approved by the Office of Air Resources prior to the performance of any compliance test.
5. The owner/operator shall install any and all test ports or platforms necessary to conduct the required compliance testing, provide safe access to any platforms, and provide the necessary utilities for sampling and testing equipment.
6. All compliance testing shall be conducted under operating conditions deemed acceptable and representative for the purpose of assessing compliance with the applicable emission limitations or air quality standards.
7. A final report of the results of compliance testing shall be submitted to the Office of Air Resources no later than 60 days following completion of the testing.
8. All compliance testing must be observed by the Office of Air Resources or its authorized representatives to be considered acceptable, unless the Office of Air Resources provides authorization to the owner/operator to conduct the testing without an observer present.

E. Recordkeeping and Reporting

1. The owner/operator shall maintain the following records:

- a. The daily average amount of ethylene oxide, in pounds, loaded into the sterilizers calculated as the amount of ethylene oxide, in pounds, loaded into the sterilizers per month divided by the number of operating days in that month.
  - b. The amount of ethylene oxide, in pounds, discharged from the entire facility per month. If the amount of ethylene oxide discharged from the entire facility in a month exceeds the allowable daily emissions specified in Condition A.4.a of this permit, the facility shall provide, to the office of Air Resources, additional supporting documentation to demonstrate that the allowable daily emissions were not exceeded during that month.
  - c. The concentration of ethylene glycol in the scrubbing liquor of the scrubber or alternatively, the scrubber liquor level in recirculation or treatment tanks. This shall be checked once per week.
  - d. The dates the scrubbing liquor is replenished for the scrubber.
  - e. The inlet and outlet temperature for the Donaldson catalytic incinerator.
  - f. The maximum ethylene glycol concentration or alternatively, the maximum scrubber liquor level and baseline temperature determined as site specific operating parameters during emission testing required under 40 CFR 63.363.
2. The owner/operator shall notify the Office of Air Resources, in writing, of the date of initial start-up of the aeration cells no later than fifteen days after start-up.
  3. The owner/operator shall notify the Office of Air Resources in writing , of any noncompliance with the terms of this permit or any other air pollution control rule or regulation within 30 calendar days of becoming aware of such occurrence and supply the director with the following information:
    - a. The name and location of the facility;
    - b. The subject source(s) that caused the noncompliance with the permit term;
    - c. The time and date of first observation of the incident of noncompliance;
    - d. The cause and expected duration of the incident of noncompliance;

- e. The estimated rate of emissions (expressed in lbs/hr or lbs/day) during the incident and the operating data and calculations used in estimating the emission rate; and,
  - f. The proposed corrective actions and schedule to correct the conditions causing the incident of noncompliance.
4. All records required in this permit shall be maintained for a minimum of five years after the date of each record and shall be made available to representatives of the Office of Air Resources upon request.
  5. The owner/operator shall notify the Office of Air Resources in writing of any planned physical or operational change to any equipment that would:
    - a. Change the representation of the facility in the application.
    - b. Alter the applicability of any state or federal air pollution rules or regulations.
    - c. Result in the violation of any terms or conditions of this permit.
    - d. Qualify as a modification under APC Regulation No. 9.

Such notification shall include:

- Information describing the nature of the change.
- Information describing the effect of the change on the emission of any air contaminant.
- The scheduled completion date of the planned change.

Any such change shall be consistent with the appropriate regulation and have the prior approval of the Director.

#### F. Other Permit Conditions

1. There shall be no bypassing of any of the air pollution control devices during times when ethylene oxide emissions are being discharged to the device.
2. To the extent consistent with the requirements of this permit and applicable federal and state laws, the facility shall be designed, constructed and operated in accordance with the representation of the

facility in the permit application dated May 3, 2010 prepared by ARCADIS.

3. Employees of the Office of Air Resources and its authorized representatives shall be allowed to enter the facility at all times for the purpose of inspecting any air pollution source, investigation any condition it believes may be causing air pollution or examining any records the Office of Air Resources requires to be maintained.
4. The owner/operator shall replace the catalyst bed with new catalyst material every 5 years, beginning December 28, 2012.
5. The owner/operator is subject to the requirements of the General Duty Clause, 40 CFR Part 68 Section 112(r)(1) of the Clean Air Act. Under this clause, the facility is responsible for but not limited to:
  - a. identifying hazards that may result from accidental releases;
  - b. designing and maintaining a safe facility; and,
  - c. minimizing the consequences of releases when they occur.
6. At all times, including periods of startup, shutdown and malfunction, the owner/operator shall, to the extent practicable, maintain and operate the facility in a manner consistent with good air pollution control practice for minimizing emissions. Determination of whether acceptable operating and maintenance procedures are being used will be based on information available to the Office of Air Resources, which may include, but is not limited to, monitoring results, opacity observations, review of operating maintenance procedures and inspection of the source.
7. The facility is subject to the requirements of 40 CFR 63, Subpart A, "General Provisions" and Subpart O, "Ethylene Oxide Emissions Standards for Sterilization Facilities". Compliance with all applicable provisions therein is required unless otherwise stated in this permit. If there is any conflict between any term or condition of this permit and the applicable provisions of 40 CFR 63, the owner/operator shall comply with the most stringent requirement.

#### G. Malfunctions

1. Malfunction means a sudden and unavoidable breakdown of process or control equipment. In the case of a malfunction of any air pollution control system, all reasonable measures shall be taken to assure resumption of the designed control efficiency as soon as possible. In the

event that the malfunction of an air pollution control system is expected of may reasonably be expected to continue for longer than 24 hours and if the owner/operator wishes to operate the source on which it is installed at any time beyond that period, the Director shall be petitioned for a variance under Section 23-23-15 of the General Laws of Rhode Island, as amended. Such petition shall include, but is not limited to, the following:

- a. Identification of the specific air pollution control system and source on which it is installed;
  - b. The expected period of time that the air pollution control system will be malfunctioning or out of service;
  - c. The nature and quantity of air contaminants likely to be emitted during said period;
  - d. Measures that will be taken to minimize the length of said period;
  - e. The reasons that it would be impossible or impractical to cease the source operation during said period.
2. The owner/operator may seek to establish that a malfunction of any air pollution control system that would result in noncompliance with any of the terms of this permit or any other applicable air pollution control rules and regulations was due to unavoidable increases in emissions attributable to the malfunction. To do so, the owner/operator must demonstrate to the Office of Air Resources that:
- a. The malfunction was not attributable to improperly designed equipment, lack of preventative maintenance, careless or improper operation or operator error;
  - b. The malfunction is not part of a recurring pattern indicative of inadequate design, operation or maintenance;
  - c. Repairs were performed in an expeditious fashion. Off-shift labor and overtime should be utilized, to the extent practicable, to ensure that such repairs were completed as expeditiously as practicable.
  - d. All possible steps were taken to minimize emissions during the period of time that repairs were performed.
  - e. Emissions during the period of time that repairs were performed will not:

- (1) Cause an increase in the ground level ambient concentration at or beyond the property line in excess of that allowed by Air Pollution Control Regulation No. 22 and any Calculated Acceptable Ambient Levels; and
  - (2) Cause or contribute to air pollution in violation of any applicable state or national ambient air quality standard.
- f. The reasons that it would be impossible or impractical to cease the source operation during said period.
- g. The owner/operator's actions in response to the excess emissions were documented by properly signed, contemporaneous operating logs or other relevant evidence.

This demonstration must be provided to the Office of Air Resources within two working days of the time when the malfunction occurred and contain a description of the malfunction, any steps taken to minimize emissions and corrective actions taken.

The owner/operator shall have the burden of proof in seeking to establish that noncompliance was due to unavoidable increases in emissions attributable to the malfunction.