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March 31, 2025

Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
airaction@epa.gov

Subject: Presidential Exemption: Ethylene Oxide Emissions Standards for Sterilization Facilities: LivaNova USA, Inc.

Dear Sirs:

On behalf of LivaNova USA, Inc. (LivaNova), we respectfully request a two-year exemption from compliance with the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Commercial Sterilizers (40 CFR Part 63, Subpart O) under Section 112(i)(4) of the Clean Air Act. Information supporting this request is provided below.

Emissions Standards or Limitations Subject to the Request:

- "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review" (89 FR 24090; April 5, 2024) (Sterilizer Rule)

Facility and Affected Sources:

- Facility Name: LivaNova Arvada Facility
- Facility Address: 14401 W 65th Way, Arvada, CO 80004
- Permit Number: 99JE0094
- AIRS ID: 059-1258
- Affected Sources:
    - Sterilization chamber vent
    - Aeration room vent
    - Chamber exhaust vent
    - Group 1 room air emissions (indoor EtO storage, EtO dispensing, vacuum pump operation)
    - Group 2 room air emissions (post-aeration handling of sterilized material)

Length of Compliance Period Being Requested:

- A two-year exemption, effective as of the compliance date of April 6, 2026, and extending through April 6, 2028.[1]

[1] LivaNova's compliance date for the Group 1 room air emissions affected source is April 5, 2027. LivaNova only requests a one-year exemption for the Group 1 room air emissions affected source, through April 6, 2028 to align with the other requested deadlines for this facility.

Justification for the Request:

1. **Technology Unavailability**:
   - The revised NESHAP requires the implementation of a permanent total enclosure (PTE) to capture all fugitive emissions. Most facilities, including LivaNova's Arvada facility, were not initially designed to implement PTE and will require substantial redesign to comply. This redesign process is technologically complex and will vary for each facility. Construction will likely be ongoing for six months or more. LivaNova also estimates that implementing PTE will result in a shut-down of its sterilization operations for six weeks or more, leaving at least an estimated 10,000 heart surgery patients without access to the care they need, that is dependent on LivaNova's sterilized medical devices.
   - There is also a scarcity of engineers and consultants capable of this type of work within the short time frame permitted under the current rule.
   - It is also unknown what the EPA will recommend or require of facilities with Ethylene Oxide sterilization operations after it reconsiders the Sterilizer Rule. Therefore, it cannot be determined at this point whether technology is currently available for this facility or whether proceeding with a technology implementation will meet the requirements that result from the EPA's reconsideration.

2. **National Security Interests**:
   - LivaNova is the only company that is domestically manufacturing and sterilizing heart surgery packs used in United States bypass surgeries. Any interruption in sterilization operations due to non-compliance could result in severe disruptions to the supply of these devices. For example, LivaNova's medical devices are used in at least 85,000 critical heart surgeries a year, and any interruption in sterilization operations would jeopardize those surgeries. Likewise, without this exemption, those 85,000 heart surgery patients are expected to be faced with increased costs for the implementation of technology that may otherwise not be needed. Ensuring the continuous availability of sterilized medical devices is vital for national health security and public safety.
   - Without this exemption, LivaNova may need to either reduce its operations or outsource its sterilization to other facilities, which could lead to further delays in providing its products for surgeries. Granting this exemption is also in the national security interests of the United States, as it will avoid any unnecessary delays if these standards change after the EPA reconsiders this rule.

Additional information supporting this request is provided in our letter to the USEPA Office of Air and Radiation dated February 21, 2025, which is incorporated by reference. We believe that granting this exemption aligns with the national security interests of the United States without compromising public health and safety.

An appropriate delegation of authority by LivaNova to submit this request is enclosed. LivaNova reserve the right to amend this application based on any subsequent guidance, rulemaking, or change in law.

We look forward to your favorable consideration of this request.

Respectfully submitted,

Bryan Michael Allen

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