

March 31, 2025

Via Electronic Mail: airaction@epa.gov

The Honorable Lee M. Zeldin
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW,
Washington, DC 20460

Re: Presidential Exemption: National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24090 (April 5, 2024) (40 CFR Part 63, Subpart O).

Dear Administrator Zeldin,

I write on behalf of Medtronic Xomed LLC (“Xomed”) to request that the President issue a two-year exemption pursuant to his authority under Clean Air Act (CAA) Section 112(i)(4) for all emission standards and associated requirements set or revised in EPA’s April 4, 2024 National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24090 (Apr. 5, 2024) (Sterilizer Rule).

Xomed requests that a Presidential Exemption be granted to the following facility for all emission sources regulated under the Sterilizer Rule contained therein:

- Xomed Jacksonville Facility, 6743 Southpoint Drive North, Jacksonville, FL, 32216, FDEP Facility ID 0310379.

Xomed further requests that the Presidential Exemption take effect according to the compliance deadlines for the applicable standards in the Sterilizer Rule, as follows:

- For standards set or revised under CAA Section 112(f) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 6, 2026 (the compliance deadline for those standards); and
- For standards set or revised under CAA Section 112(d) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 5, 2027 (the compliance deadlines for those standards).

As explained further in the attached letter submitted to EPA on March 17, 2025, on behalf of the Ethylene Oxide Sterilization Association (EOSA), the technology necessary to implement the standards set forth in the Sterilizer Rule is not available because manufacturers cannot guarantee

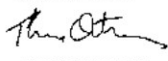
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that existing emissions control equipment will enable sources to meet the new standards; there is not a sufficient supply of the necessary control and monitoring technology; and there are not enough experienced installation professional and technical experts to install and test that equipment within the current compliance timeframes.

As also explained further in EOSA's March 17 letter, it is in the national security interests of the United States to issue the requested exemption because if the Xomed Jacksonville Facility is forced to cease operations on April 6, 2026, that will disrupt the supply of sterilized medical devices, raise the cost of those devices, and/or force medical suppliers or providers to source sterilized medical devices from abroad.

If EPA requires additional information regarding the Xomed Jacksonville Facility, including the availability of technology to comply with the Sterilizer Rule or national security risks if the Facility is forced to cease operations, we would be pleased to provide additional information as needed to fully support this request for Presidential Exemption. Please contact me if EPA has any questions or concerns regarding Xomed's request. Xomed appreciates EPA's attention to this important matter. I can be reached by phone at (904) 296-6456 or email tim.romecki@medtronic.com if EPA requires any additional information not act on the requested exemption.

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Thomas Osteraas
Officer
Medtronic Xomed LLC

Enclosure:

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