195 McDermott Road
North Haven, CT 06473

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March 31, 2025
Via Electronic Mail: airnetbox@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):

- **Covidien North Haven Facility, 195 McDermott Road, North Haven, Connecticut**

Dear Administrator Zeldin:

Covidien LP ("Covidien") hereby submits the following request for Presidential Exemption from the final risk and technology review of the National Emission Standards for Hazardous Air Pollutants ("NESHAP") for the commercial ethylene oxide ("EtO") sterilization source category, 40 CFR Part 63, Subpart O ("Sterilizer Rule"), published in the Federal Register on April 5, 2024.[1] On March 12, 2025, the U.S. Environmental Protection Agency ("EPA") announced the "Powering the Great American Comeback Initiative" to, among other actions, reconsider the Sterilizer Rule and other standards affecting a broad range of American industrial sectors. The enclosed request is submitted in accordance with EPA's instruction to submit requests for Presidential Exemptions from the Sterilizer Rule by March 31, 2025.[2]

I. Request for Presidential Exemption

Covidien has determined that its medical device manufacturing and sterilization facility located at 195 McDermott Road, North Haven, Connecticut ("North Haven Facility" or "Facility") cannot implement certain requirements of the Sterilizer Rule before the applicable compliance date. Specifically, it is *technologically infeasible* to install the Facility upgrades needed to operate a Permanent Total Enclosure ("PTE") for all Group 2 room air emissions (as defined in the Sterilizer Rule) prior to April 6, 2026. If the North Haven Facility is forced to halt sterilization operations on the compliance date, there is no available alternative to safely sterilize the essential medical products manufactured by Covidien. Therefore, a disruption to the sterilization operations

[1] 89 Fed. Reg. 24090 (Apr. 5, 2024).
[2] EPA, "Clean Air Act Section 112 Presidential Exemption Information," available at, https://www.epa.gov/stationary-sources-air-pollution/clean-air-act-section-112-presidential-exemption-information.

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of the North Haven Facility would adversely affect the United States' *national security interest* in a safe and reliable domestic supply of sterile medical products.

In accordance with Section 112(i)(4) of the Clean Air Act, Covidien requests a Presidential Exemption to extend the North Haven Facility's deadline to comply with all standards for Group 2 room air emissions under the Sterilizer Rule for ***two years until April 5, 2028***.

A. Background

The Covidien North Haven Facility is a finished goods manufacturing and assembly plant for Class I, II, and III medical devices, primarily to serve the surgical market.[3] The majority of products produced at the North Haven Facility undergo EtO sterilization as part of the standard manufacturing process. A proportion of products are made from bio-absorbable materials or contain bio-absorbable materials that are sensitive to moisture and other outside elements. Those products that are absorbable in nature, or that contain absorbable elements, are sterilized on-site to ensure product performance and shelf life. As described further below, these products require additional post-sterilization processing and packaging on-site in the North Haven Facility before being distributed for sale.

Products manufactured and EtO sterilized at the North Haven Facility include:

Product	Description	EtO Sterilized On-Site	Post-Aeration Processing On-Site
V-Loc™ Wound Closure Device	Barbed sutures, absorbable and non-absorbable	X	X
Polysorb™ Braided Absorbable Suture	Braided absorbable suture	X	X
AbsorbaTack™ Fixation Device	Absorbable tack fixation device for laparoscopic hernia repair	X	X

[3] The U.S. Food and Drug Administration ("FDA") requires medical devices to be classified based on the risk posed to a patient associated with the intended use or specialized indications for use of a device. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

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Product	Description	EtO Sterilized On-Site	Post-Aeration Processing On-Site
ReliaTack™ Articulating Reloadable Fixation Device	Articulating absorbable tack fixation device for laparoscopic hernia repair	X	X
MaxTack™ Motorized Fixation Device	Motorized absorbable tack fixation device for laparoscopic hernia repair	X	X
Tri-Staple™ 2.0 Reinforced Reload	Endoscopic stapling instrument with absorbable buttress material	X	X
Endo GIA™ Reload with Tri-Staple™ Technology and Tri-Staple™ 2.0 Reload	Endoscopic stapling instruments	X	
Lapro-Clip™ Absorbable Clips	Absorbable ligation clips	X	X
Premium Poly CS™ Stapler	Absorbable open stapler	X	X

The North Haven Facility currently operates two sterilization systems, each consisting of a sterilization chamber, and a primary aeration room. Secondary aeration rooms are also available and can be shared by both systems. The two sterilizer systems are currently permitted by the Connecticut Department of Energy and Environmental Protection ("CTDEEP") under state New Source Review ("NSR") Permit Nos. 135-0143 & 135-0144. NSR Permit No. 135-0143 covers Sterilizer No. ST-A, and NSR Permit No. 135-0144 covers Sterilizer No. ST-B. Medical devices manufactured onsite are sterilized using a mixture of EtO, nitrogen, and steam. Sterilized product is then aerated. All exhausts and vents from both systems, including the sterilization chambers, primary aeration, and secondary aeration are ducted to a single stack equipped with a balancer and catalytic oxidizer.

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B. The technology needed for the North Haven Facility to comply with Group 2 room air emission control requirements is not available prior to the applicable compliance date

The Sterilizer Rule requires the North Haven Facility identify a compliance approach, design physical modifications, procure control technologies, and complete construction of Facility upgrades to comply with new emission standards applicable to Sterilization Chamber Vents ("SCVs"), Aeration Room Vents ("ARVs"), Chamber Exhaust Vents ("CEVs"), and Group 1 and Group 2 room air emissions.[4] Group 1 room air emissions apply to "emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material."[5] Group 2 room air emissions apply to "emissions from . . . the storage and transportation of material that has been removed from aeration but has not been placed in a vehicle for the sole purpose of distribution to another facility."[6] Covidien plans to install PTEs for all areas within the North Haven Facility identified as containing Group 1 and Group 2 room air emissions, two banks of dry resin bed control device systems with at least 80% DRE, and new stacks associated with the two dry bed systems. The North Haven Facility is currently permitted for a combined EtO throughput of greater than 4 tons per year (tpy) and, therefore, must comply with Group 2 emission standards promulgated under Clean Air Act Section 112(f)(2) by April 6, 2026.

Below is a representative process flow diagram of the planned system for controlling Group 1 or Group 2 room air emissions:

[4] This request for Presidential Exemption does not seek an extension of time to comply with the standards for SCVs, CEVs, or ARVs under the Sterilizer Rule.
[5] 40 CFR 63.361
[6] *Id.*

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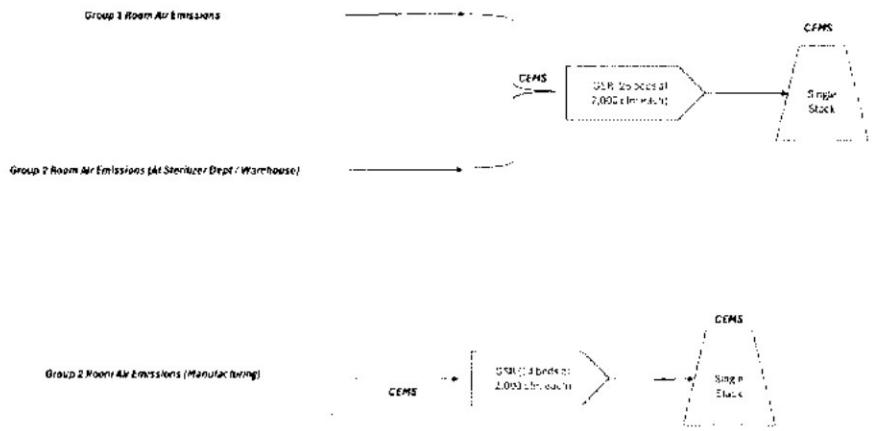
North Haven Facility Group 1 and Group 2 Planned Process Flow Diagram



The Group 1 room air emissions routed to the first dry resin bed system comprise EtO storage, dispensing, vacuum pump operations, and pre-aeration handling of sterilized material consistent with the scope of Group 1 emission sources defined under the Sterilizer Rule. The Group 2 room air emissions (sterilizer department / warehouse operations) routed to this system comprise post aeration handling of sterilized product prepared for additional processing onsite or for shipment off site. In addition, Group 2 room air emissions (manufacturing) routed to the second dry resin bed system comprise post-aeration processing operations for bioabsorbable sutures manufactured at the North Haven Facility. These operations occur in several different areas of the Facility, including dry rooms with various processes designed to remove moisture from the suture products and maintain dry conditions prior to final packaging for distribution.

Covidien has determined that it is *technologically infeasible* to design and install PTEs for Group 2 room air emissions within the extremely short compliance deadline of April 6, 2026 finalized by EPA in the Sterilizer Rule. Several engineering challenges at the North Haven Facility make the compliance deadline for controlling Group 2 room air emissions technologically infeasible.

First, manufacturing areas used to process post-aeration sterilized material include distinct room areas that are physically disconnected and located on separate floors. The hallways, elevator and other corridors connecting all Group 2 areas cannot be contained within a single PTE due to physical separation, adjoining hallways and spaces, varying ceiling heights, and utilities located through these spaces. Multiple air locks or vestibules would be needed to control air flow from one or more PTEs. Further, as a combined manufacturing and sterilization Facility, the building includes numerous operations adjacent to or surrounding Group 2 areas that do not handle post-

aeration sterilized material. Several such areas require clean room environments and/or dry room environments with positive air pressure gradients that are inconsistent with the design of a PTE. As a consequence, a PTE for the Group 2 areas must include numerous Natural Draft Openings ("NDOs") to common hallways or other areas of the North Haven Facility. The engineering challenges associated with designing a PTE for this facility make the April 6, 2026 compliance deadline infeasible.

Second, maintaining negative air pressure through the substantial volume of duct work that would be needed for a PTE will be highly energy *inefficient*. It is anticipated that the North Haven Facility will need to substantially redesign its heating and cooling systems to facilitate the necessary air pressure gradient and large volume of air exhausted from the building.

Third, Covidien's bioabsorbable suture products require post-aeration drying to remove moisture from steam used during the sterilization process. Group 2 areas that include dry rooms must be maintained at positive air pressure to remove moisture for product quality purposes. Therefore, EPA Method 204 was developed for single-room or facility-wide operations that are not readily transferrable to the North Haven Facility's combination medical device manufacturing and sterilization operations. Covidien specifically raised these serious concerns in comments responding to EPA's proposed revisions to the Sterilizer Rule, explaining:

> PTEs are not feasible for sterilizers located at medical device manufacturing plants in light of the dual nature of the activities being conducted at such facilities. PTEs would require that sterilization and manufacturing operations within the same facility to be kept under negative and positive pressure environments, respectively. This arrangement would potentially require significant changes to the overall ventilation system, which would be infeasible to implement within a single facility (depending upon the individual facility configuration). It may also disrupt or prevent certain manufacturing operations that require clean room environments with air pressure gradients that are inconsistent with the design of a PTE.[7]

In summary, the North Haven Facility faces specialized challenges to complying with the Group 2 emissions requirements because of the products manufactured and sterilized at this Facility. As a result, Covidien has determined that that it is technologically infeasible to design the physical modifications, amend NSR Permit Nos. 135-0143 and 135-0144, procure necessary control equipment, complete construction, and conduct initial performance tests prior to the April 6, 2026 to control Group 2 room air emissions. *See* 42 U.S.C. § 7412(i)(4) ("the President may

[7] EPA-HQ-OAR-2019-0178-0577 (comment submitted by Covidien's corporate parent, Medtronic Inc.).

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exempt any stationary source from compliance with any [NESHAP] standard or limitation . . . if the President determines that ***the technology to implement such standard is not available*** . . .").

C. Any disruption or temporary pause to the supply of essential products manufactured by the North Haven Facility will threaten patient health and safety and, therefore, national security

The U.S. government has recognized that medical device manufacturing and sterilization operations are vital to domestic critical infrastructure. Incapacitation or disruption to these operations would have a debilitating effect on national security, economic security, public health and safety, or any combination thereof. Indeed, the U.S. Department of Homeland Security, Cybersecurity and Infrastructure Agency ("CISA") has determined:

> The Healthcare and Public Health Sector protects all sectors of the economy from hazards such as terrorism, infectious disease outbreaks, and natural disasters. Because the vast majority of the sector's assets are privately owned and operated, collaboration and information sharing between the public and private sectors is essential to increasing resilience of the nation's Healthcare and Public Health critical infrastructure.[8]

A reliable supply of sterile medical devices and equipment sterilized using EtO—such as sutures, surgical kits, IV sets, and other equipment—is critical to the United States' national security interests' because these products are subject to highly inelastic demand. There are nearly 6,100 hospitals in the United States which admit more than 34.4 million patients annually.[9] Medical devices and equipment respond to "on demand" and unpredictable healthcare needs. Any disruption to the supply of medical devices roughly 50% of which are sterilized using EtO[10] would adversely affect patient care. Healthcare associated infections are also a major public health concern in the United States and worldwide. In the United States alone, it is estimated that 1 in 31 patients (more than 1 million patients per year) experience healthcare associated infections.[11] Along with infection control practices, effective sterilization of medical devices and instruments is essential to minimize the risk of healthcare associated infections.

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[8] CISA, "Healthcare and Public Health Sector", available at https://www.cisa.gov/topics/critical-infrastructure-security-and-resilience/critical-infrastructure-sectors/healthcare-and-public-health-sector.

[9] American Hospital Association, "Fast Facts on U.S. Hospitals, 2025," available at https://www.aha.org/statistics/fast-facts-us-hospitals.

[10] U.S. FDA, "Sterilization for Medical devices," available at https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices.

[11] U.S. Centers for Disease Control and Prevention, "2023 National and State Healthcare-Associated Infections Progress Report," available at https://www.cdc.gov/healthcare-associated-infections/php/data/progress-report.html.

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The bioabsorbable sutures manufactured by Covidien provide lifesaving medical care to patients throughout the United States. If Covidien is forced to halt or terminate sterilization operations at the North Haven Facility, the resulting disruption to domestic supply of bioabsorbable sutures would adversely impact the public health critical infrastructure of the United States. Moreover, if Covidien cannot continue to conduct sterilization operations in America, it may be forced to seek manufacturing and/or sterilization capacity outside the United States. Reliance on imported medical equipment poses a *national security risk* because disruption due to geopolitical conflicts, trade restrictions, economic coercion, or other factors could severely limit the resilience of United States' healthcare system. Therefore, the requested exemption is in the national security interests of the United States. *See* 42 U.S.C. § 7412(i)(4) ("the President may exempt any stationary source from compliance with any [NESHAP] standard or limitation . . . if the President determines that . . . ***it is in the national security interests of the United States to do so***. . .").

II. Conclusion

For the reasons explained herein, Covidien respectfully requests a Presidential Exemption to extend the compliance deadline to comply with all standards for Group 2 room air emissions at the North Haven Facility. Subject to EPA's reconsideration of the Sterilizer Rule, Covidien seeks a two-year exemption until April 5, 2028.

We would be pleased to address any questions regarding this request for Presidential Exemption. Please direct any inquiries to my attention at thomas.l.osteraas@medtronic.com.

Signed by:
Thomas L. Osteraas
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Thomas L. Osteraas
Officer
Covidien LP

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