



REGULATORY RELIEF FOR CERTAIN STATIONARY SOURCES TO PROMOTE
AMERICAN SECURITY WITH RESPECT TO STERILE MEDICAL EQUIPMENT
10959
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BY THE PRESIDENT OF THE UNITED STATES OF AMERICA

A PROCLAMATION

1. The use of ethylene oxide is critical for the sterilization of medical equipment, which protects patients against infection and the transmission of disease. The continued utilization of ethylene oxide by commercial sterilization facilities is essential to ensuring that our Nation provides its sick and injured with the best outcomes possible -- an objective that is at the forefront of the Federal Government's responsibility to the American people.

2. On April 5, 2024, the Environmental Protection Agency published a final rule, pursuant to section 112 of the Clean Air Act, 42 U.S.C. 7412, titled *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, 89 FR 24090 (EtO Rule). The EtO Rule imposes new emissions-control requirements on commercial sterilization facilities.

3. The EtO Rule places severe burdens on commercial sterilization facilities. About 50 percent of all sterile medical devices in the United States are sterilized with ethylene oxide, and sterilization with ethylene oxide may be the only method of sterilizing many medical devices without damaging them. By requiring compliance with standards premised on the application of emissions-control technologies that do not exist in a commercially viable form, the EtO Rule risks making critical sterile medical devices unavailable to care for patients in our civilian and military medical systems. The current compliance timeline as set forth at 89 FR 24101-24103 of

the EtO Rule will likely force existing sterilization facilities to close down, seriously disrupting the supply of medical equipment. Our Nation would be unable to adequately supply the sterilized medical equipment that medical personnel need to safely treat their patients in hospitals, operating rooms, and other medical facilities. In short, the current compliance timeline would undermine our national security.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States, including section 112(i)(4) of the Clean Air Act, 42 U.S.C. 7412(i)(4), do hereby proclaim that certain stationary sources subject to the EtO Rule, as identified in Annex I of this proclamation, are exempt from compliance with the EtO Rule for a period of 2 years beyond the EtO Rule's relevant compliance dates (Exemption). This Exemption applies to all compliance deadlines established under the EtO Rule applicable to the stationary sources listed in Annex I, with each such deadline extended by 2 years from the date originally required for such deadline. The effect of this Exemption is that, during each such 2-year period, these stationary sources will remain subject to the emissions and compliance obligations in effect prior to the issuance of the EtO Rule. In support of this Exemption, I hereby make the following determinations:

- a. The technology to implement the EtO Rule is not available. Such technology does not exist in a commercially viable form sufficient to allow implementation of and compliance with the EtO Rule by the compliance dates set forth in the EtO Rule.

b. It is in the national security interests of the United States to issue this Exemption for the reasons stated in paragraphs 1 and 3 of this proclamation.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of July, in the year of our Lord two thousand twenty-five, and of the Independence of the United States of America the two hundred and fiftieth.

ANNEX I

1. International Sterilization Laboratory
 - i. Affected Facility/Source: Groveland Facility, Florida
2. Becton Dickinson and Company
 - i. Affected Facility/Source:
 - a. BD Covington, Georgia
 - b. BD Madison, Georgia
 - c. BD Medical, Utah
 - d. BD Medical Pharmaceutical Systems, Nebraska
 - e. Edwards Lifesciences Technology Sàrl, Puerto Rico
3. KPR US, LLC d/b/a Kendall Patient Recovery
 - i. Affected Facility/Source: Augusta Facility, Georgia
4. MedXL, LLC
 - i. Affected Facility/Source: Ardmore Facility, Oklahoma
5. Aligned Medical Solutions
 - i. Affected Facility/Source:
 - a. 1602 4th Ave. Facility, Billings, Montana
 - b. 1400 Montana Ave. Facility, Billings, Montana
6. Professional Contract Sterilization, Inc.
 - i. Affected Facility/Source: Taunton Facility,
Massachusetts
7. Sterigenics U.S., LLC
 - i. Affected Facility/Source:
 - a. Atlanta Facility, Georgia
 - b. Charlotte Facility, North Carolina
 - c. Grand Prairie Facility, Texas
 - d. 4900 S Gifford Ave. Facility, Los Angeles,
California
 - e. 4801-63 E 50th St. Facility, Los Angeles,
California
 - f. Ontario Facility, California
 - g. Queensbury Facility, New York
 - h. Salt Lake City Facility, Utah
 - i. Santa Teresa Facility, New Mexico
8. Cosmed Group, Inc.
 - i. Affected Facility/Source:
 - a. Erie Facility, Pennsylvania
 - b. Franklin Facility, New Jersey
 - c. Linden Facility, New Jersey
9. Arthrex
 - i. Affected Facility/Source: Ave Maria Facilities (2),
Florida

10. Cook Incorporated
 - i. Affected Facility/Source: Ellettsville North Facility, Indiana
11. ALCON Research Ltd.
 - i. Affected Facility/Source: ALCON Advance Optic Device Center, North Facility, West Virginia
12. B. Braun U.S. Device Manufacturing LLC
 - i. Affected Facility/Source: Allentown Manufacturing Facility, Pennsylvania
13. DeRoyal Industries, Inc.
 - i. Affected Facility/Source:
 - a. 1135 Highway 33 South, New Tazewell, Tennessee
 - b. 1211 Highway 33 South, New Tazewell, Tennessee
14. Sterilization Services of Georgia, Inc.
 - i. Affected Facility/Source: Atlanta Facility, Georgia
15. Sterilization Services of Virginia, Inc.
 - i. Affected Facility/Source: Richmond Facility, Virginia
16. Trinity Sterile, Inc.
 - i. Affected Facility/Source: Trinity Sterile, Inc., Maryland
17. LivaNova USA, Inc.
 - i. Affected Facility/Source: LivaNova Arvada Facility, Colorado
18. Covidien LP
 - i. Affected Facility/Source: Covidien North Haven Facility, Connecticut
19. Medtronic Xomed LLC
 - i. Affected Facility/Source: Jacksonville Facility, Florida
20. Medtronic Puerto Rico Operations Company, Inc.
 - i. Affected Facility/Source:
 - a. Villalba Facility, Puerto Rico
 - b. Juncos Facility, Puerto Rico
21. Advanced Product Solutions
 - i. Affected Facility/Source: Columbia Facility, Alabama
22. Steri-Tech, Inc.
 - i. Affected Facility/Source: Salinas, Puerto Rico