

Message

From: AirAction [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA78B98923384078995E04A73D258D83-AIRACTION]
Sent: 3/31/2025 3:31:09 PM
To: David Howe [dhowe@cosmedgroup.com]
Subject: RE: Presidential exemption: Sterilizer Rule (89 FR 24090): All facilities owned by Cosmed Group, Inc., Jamestown, RI

Thank you for emailing the AirAction mailbox to request a Presidential Exemption under section 112(i)(4) of the Clean Air Act and for engaging with EPA in advancing President Trump's Executive Orders and Powering the Great American Comeback. We have received your email and will be in contact soon. If you have Confidential Business Information (CBI) that you'd like to submit, please submit it in electronic version to the CBI@epa.gov inbox or in hardcopy to:

USEPA, OAQPS
CORE CBI Office
4930 Old Page Road
Durham, NC 27703

From: David Howe <dhowe@cosmedgroup.com>
Sent: Monday, March 31, 2025 11:23 AM
To: AirAction <AirAction@epa.gov>
Cc: Deborah Lent <Deborah.Lent@cosmedgroup.com>; Karen Burns <kburns@cosmedgroup.com>; Christine Render <crender@cosmedgroup.com>
Subject: Presidential exemption: Sterilizer Rule (89 FR 24090): All facilities owned by Cosmed Group, Inc., Jamestown, RI

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To: airaction@epa.gov

Re: Presidential exemption: Sterilizer Rule (89 FR 24090): All facilities owned by Cosmed Group, Inc., Jamestown, RI

Cosmed Group, Inc. (Cosmed) hereby requests that the President issue a two-year exemption pursuant to his authority under 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 FR 24090 (April 5, 2024) (Sterilizer Rule).

Cosmed requests that the requested Presidential exemption apply to the following facilities regulated by the Sterilizer Rule and all sources therein:

- Cosmed Group, Inc., d/b/a Cosmed of Pennsylvania, 2205 East 33rd Street, Erie, PA, FRS ID 110000332015
- Cosmed Group, Inc., d/b/a Cosmed of New Jersey, 19 Park Drive, Franklin, NJ, FRS ID 110070557911
- Cosmed Group Inc., 2500 Brunswick Avenue, Linden, NJ, FRS ID 110000318567

Cosmed requests that the President issue a two-year exemption as quickly as possible but designate the exemption as taking effect beginning on the compliance deadlines for the standards in the Sterilizer Rule.

Specifically, (1)

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 (2) 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).

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2025-EPA-04883

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Cosmed conducts ethylene oxide sterilization operations at the facilities identified above and is a member of the Ethylene Oxide Sterilization Association (EOSA). As explained further in the attached letter submitted to EPA on March 17, 2025 on behalf of the EOSA, the technology necessary to implement the standards set forth in the Sterilizer Rule is not available because manufacturers cannot guarantee that existing emissions control equipment will enable sources to meet the new standards, there is not a sufficient supply of the necessary technology, and there are not enough experienced installation professionals and technical experts to install and test that equipment within the compliance timeframes specified in the Sterilizer Rule.

As also explained further in EOSA's March 17, 2025 letter, it is in the national security interests of the United States to issue the requested exemption because if some facilities choose to cease operations rather than attempt compliance (which seems likely), 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.

Please do not hesitate to contact us if additional information is needed. Cosmed appreciates EPA's attention to this important matter and urges EPA to recommend that the President issue the requested exemption as quickly as possible.

Cosmed Group, Inc.
Debtor in Possession

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