

Ethylene Oxide (EtO)  
Sterilization at

# BLUE LINE

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# Blue Line Sterilization Background



Before our founding in 2009, no one in the medical device sterilization industry was focused on **fast turnaround** and small loads. We were the first and we're proud to serve this niche better than anyone else. We were also the first to focus on the unique needs of startup medical device manufacturers.



**Innovation** in how we meet challenges and customer needs has a lot to do with why we succeed. Our unwavering commitment — combined with our expertise and agile company culture — enables us to think outside the box. Customers appreciate that we are creative and innovative (and always compliant) in serving their needs and meeting deadlines.

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# Blue Line Sterilization Services

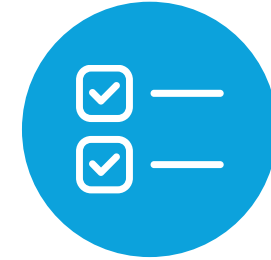
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Turnkey validation and batch releases



Comparative resistance studies



Sterilization project management



Support for clinical trials and product launches



R&D and commercial release sterilization

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# In-house Steri-Vac Sterilizers

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## Sterilizer Highlights

- Physical parameter display on screen
- In-chamber timed aeration
- Pre-set or programmable cycle
- Wide range of set-points for critical parameters
- 100% Ethylene Oxide
- 16 x 18 x 36 in. workable dimensions

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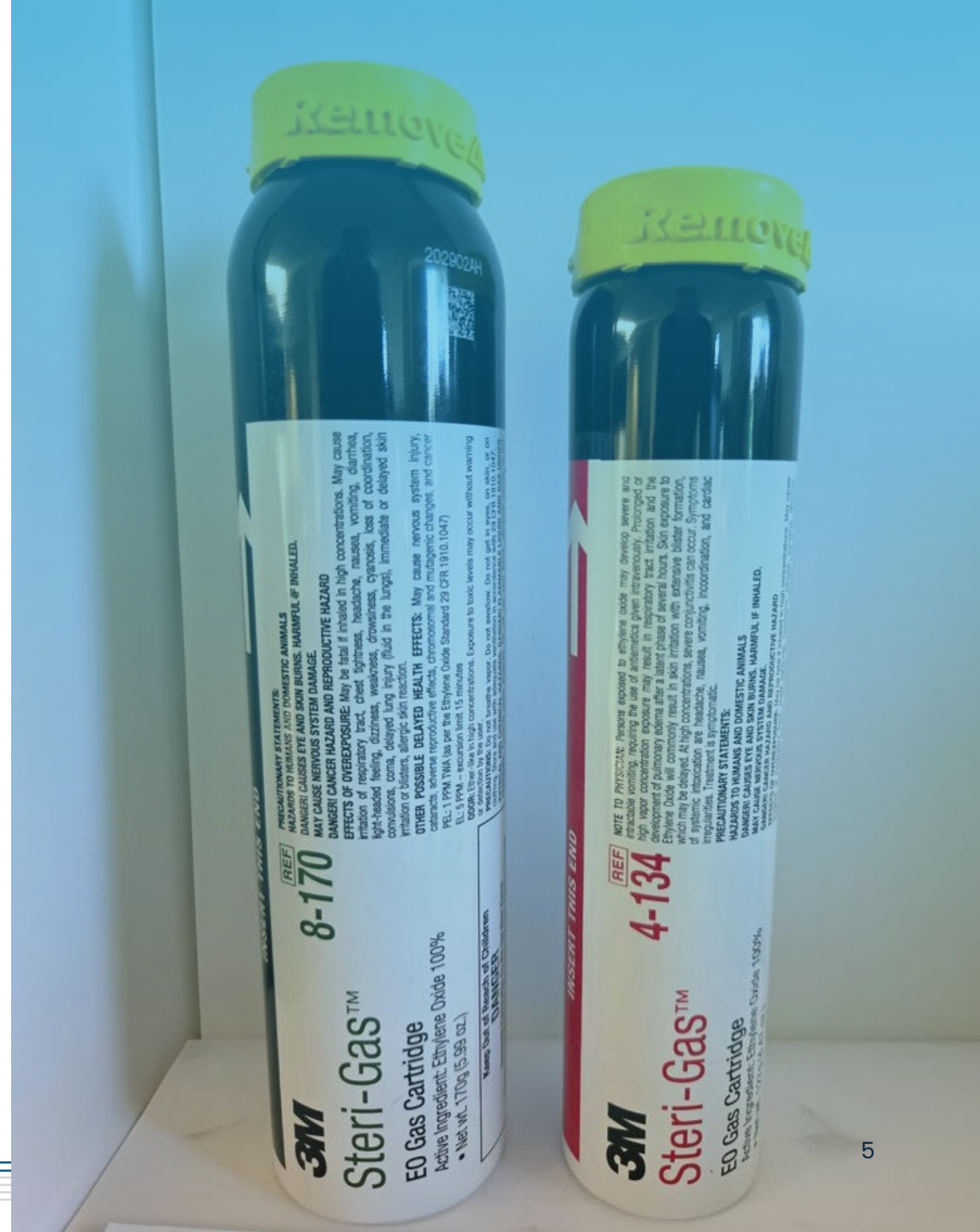


# Blue Line Gas Sterilant

- 100% EO (EtO)
- Multiple EO Concentration Ranges
  - Gas Cartridge - 4-134 (545-586 mg/L)
  - Gas Cartridge - 8-170 (720-790 mg/L)
- Self contained EO process
- Gas scrubbed (burned off) at 99.97% post –processing
- Meets new EPA rule requirements

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# Industry Leading Service Levels

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Lead Times for routine processing:

**Base Time**  
**3** Days maximum

**Rush**  
**2** Days maximum

**Express**  
**1** Next day

**Overnight\***  
**12** Hours

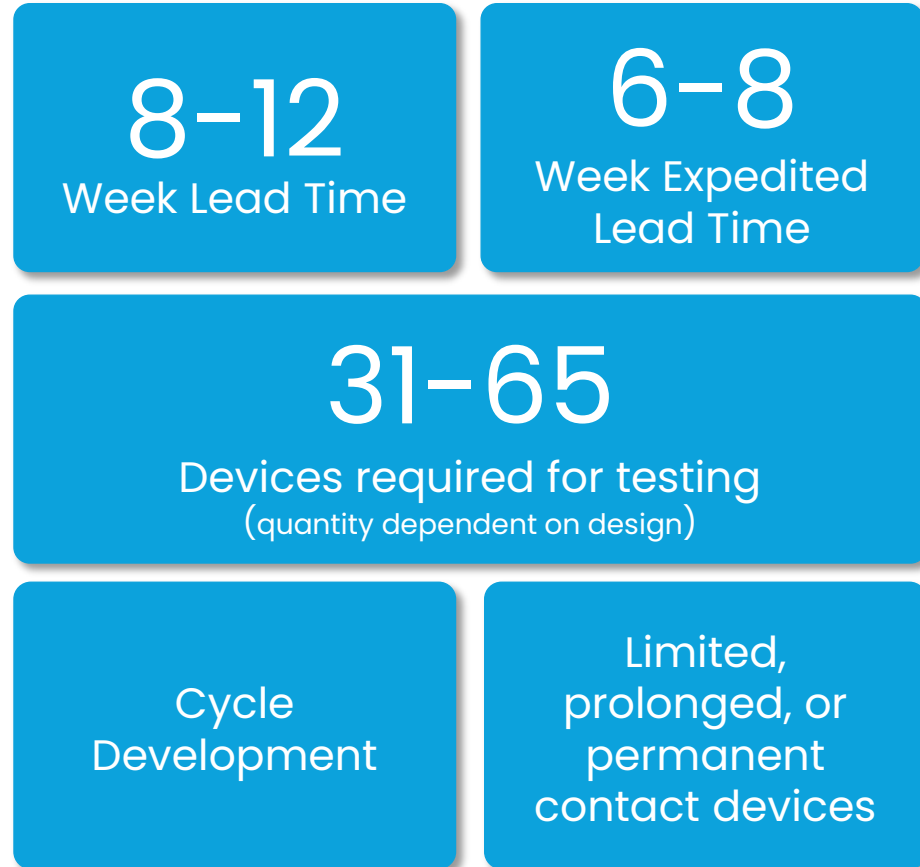
\*Cycle time permitting and courier service required to qualify for overnight service

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# ISO1135 Sterilization Validations

Requirements for Batch Release:



Includes

- Protocol & Report
- Project Consultation
- BI Location Determination and Placement
- Sterilizer IQ/OQ/Calibration Reports
- Required Equipment Calibrations
- PCDs or Biological Indicators
- Chemical and Microbial Test Reports
- SAL Calculation
- Sterilization Run Documentation
  - History Records
  - Certificate of processing
  - BI Test Reports
  - Datalogger results

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