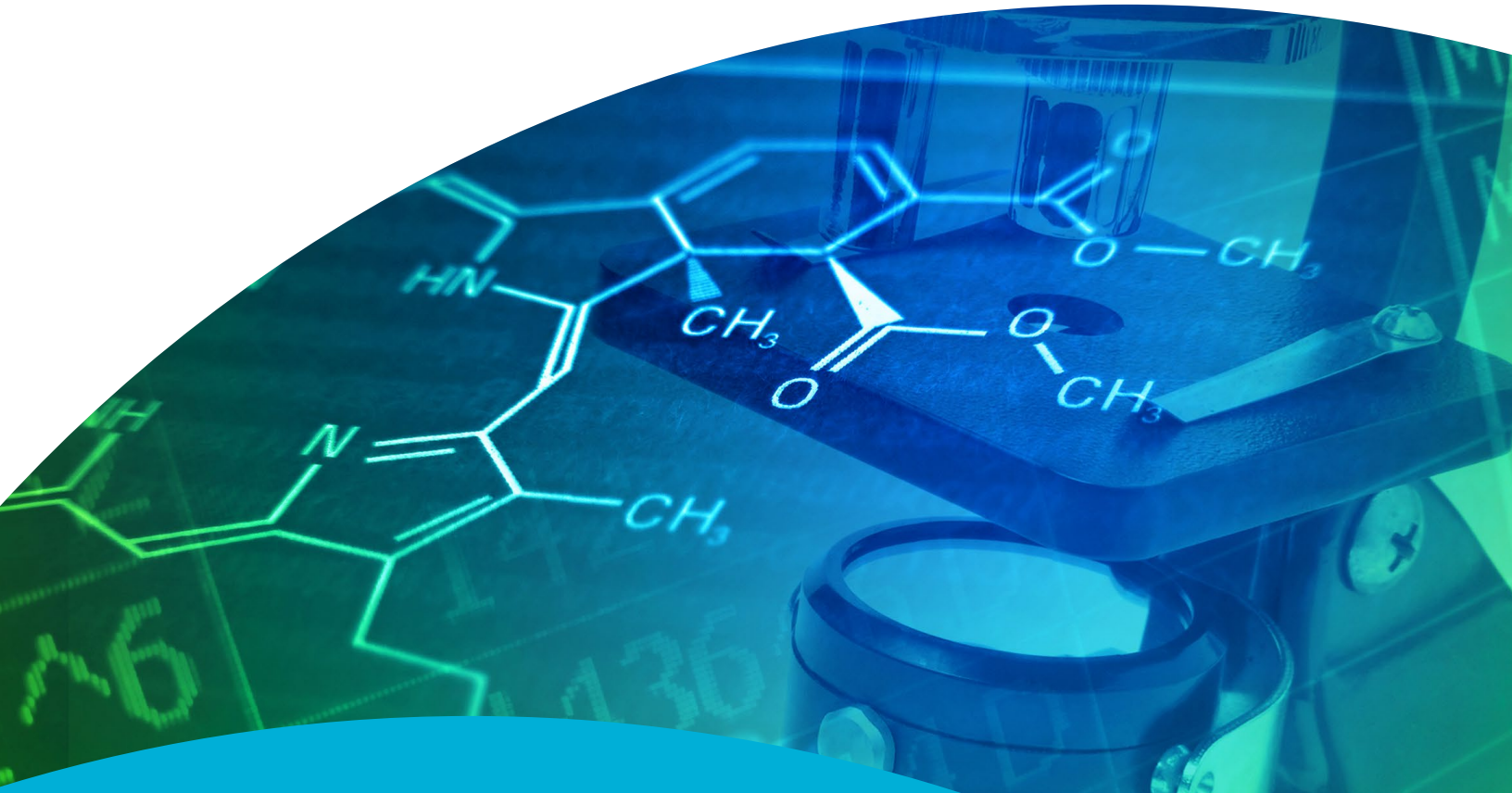
Sterigenics®
A Sotera Health company

Stored Energy Device Safety Assessment for Ethylene Oxide Sterilization



The Global Leader in Comprehensive Sterilization Solutions

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Stored Energy Device Safety Assessment for Ethylene Oxide Sterilization

Primary device information is required for analysis including product specifications, design details, use information and a product sample.

The safety assessment is performed on the device in worst case and single point failure probability of ignition. This is done to insure any energy contained within or generated by a device is incapable of igniting EO in the chamber via mechanical, chemical or electrical means.

Results from a standard analysis are available in 4-8 weeks.

- An approval allows for use of Sterigenics approved "battery cycles" for sterilization in Sterigenics chambers. The approval is limited to use in Sterigenics chambers only and cannot be used elsewhere.

Expert Advisory Services are also available in the design process to steer where possible device design to market with speed and ease by minimizing ignition potential within the finished product.

Contact your Sterigenics Account Manager to discuss the need for a Stored Energy Device Safety Assessment for EO sterilization. Call **(800) 472-4508** or go to **sterigenics.com**

Rapid innovation in the medical device technology and booming demand in healthcare has fueled the growth of battery-powered devices to improve product quality and patient outcomes.

Ethylene oxide (EO) is the most common industrial sterilization technique for medical devices due to its high compatibility with most materials used in the manufacture of medical devices and effectiveness driven by a lethal chemical reaction (alkylation) with the DNA of bacteria, viruses, molds, yeasts and even insects. The process involves exposing the medical device to EO gas under a vacuum in a sealed chamber. When using EO gas to sterilize medical devices with batteries or other energy containing components a thorough assessment must be conducted to ensure the safety of the facility, staff, customers, product, and the community.

Due to concerns with EO ignition, Sterigenics by policy and regulations cannot place devices that store energy into EO chambers without first conducting a full Safety Assessment led by senior EO Technical, Engineering and EH&S experts.

Stored Energy Device Safety Assessment Checklist
Manufacturer's name
Unique manufacturer part number, or identifier
Description/claims to be used in promotion to denote this specific device
Device operating instructions
Battery specifications
Details of any battery isolation means (i.e., switches, pull tabs, separated battery pack)
Electrical schematics including highest voltages in the device
Component listing (e.g., capacitor 100 pF, inductor 20mH, resistor 120 ohms)
Name and contact information for technical clarification on energy levels within the device
Other technical information/specifications as requested to support analysis including device, if necessary

For more information see EOSA (ethylene oxide sterilization association) considerations for Sterilizing Battery-Powered Devices info and powered component safety review checklist http://www.eosa.org/sites/default/files/EOSA%20Battery%20Device%20Guidelines1.pdf

Safety is a core value of Sterigenics. We are uncompromising in our commitment to health and well-being. This is the strategy behind all Environmental Health and Safety (EH&S) initiatives – to help protect our employees and customers.

Comprehensive Sterilization Solutions

We are over 1600 engineers, scientists, safety specialists and solution providers focused on eliminating threats to the health of humanity. We have global breadth and more than 90 years of deep expertise across Gamma, EO, Ebeam and X-ray sterilization. Our operations span 47 facilities in 13 countries to ensure we are the "point of safe" for our customers.

Safeguarding Global Health™ – with every product we sterilize.

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