Stored Energy Device Safety Assessment for Ethylene Oxide Sterilization

The Global Leader in Comprehensive Sterilization Solutions

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.

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**Stored Energy Device Safety Assessment Checklist**

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

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**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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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

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