Indications for Use

The EOGas 4 Endo-SteriTest consists of a self-contained biological indicator inoculated with viable Bacillus atrophaeus bacterial spores that is placed in a dedicated biological indicator receptacle mounted on a gold-colored purge probe in the sterilizer. It monitors the efficacy of the 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.

Critical process parameters for the cycle are summarized in Table 1.

Table 1. Critical parameters for the 6-hour gas exposure in the EOGas 4 Ethylene Oxide Gas Sterilizer

<table>
<thead>
<tr>
<th>Ethylene Oxide</th>
<th>Temperature</th>
<th>Relative Humidity</th>
<th>EO Exposure Time</th>
<th>Total Cycle Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.6 g ± 5%</td>
<td>50°C ± 3°C</td>
<td>35-90%</td>
<td>6 hours</td>
<td>7 hours</td>
</tr>
</tbody>
</table>

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)  ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer  
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