

## Gas-Chex<sup>®</sup> Indicator Strips

Technical Data Sheet

November 2017

Propper Gas-Chex<sup>®</sup> Sterilization Indicator Strips are chemical indicators designed to monitor all critical sterilization parameters of Ethylene Oxide (EO, or EtO) gas sterilization in Healthcare facilities and industrial applications.

Propper Gas-Chex<sup>®</sup> Strips monitor the following critical parameters of the process: EO gas concentration, exposure time, temperature and humidity. If any of the critical parameters will be insufficient, the indicator will not change to the green end-point color.

### The indicator has the following stated values (s.v.):

As per ISO 11140-1:2014, stated values are indicator performance parameters determined in a special testing sterilizer - Resistometer (BIER vessel). For Gas Chex<sup>®</sup> strips stated values are as follows:

54°C, 600 mg/l EO, 60±10% R.H., 40 min.  
38°C, 600 mg/l EO, 60±10% R.H., 100 min

The performance parameters of Gas-Chex<sup>®</sup> Sterilization Indicator strips meet the requirements of ISO 11140-1 for Class 5 indicator. The indicator performance is equivalent to the performance of biological indicators.

### Indicator color change and result interpretation:

Gas-Chex<sup>®</sup> indicators strips have easy-to-remember color scheme: **Red** for **Stop** (pack was not yet processed or the process was inadequate), and **Green** for **Go**. Any shade of green is considered a Pass result. If at the end of sterilization the color of the indicator is not green – red, yellow or brown, the result is Fail.

### Ink safety testing:

The indicator ink has been tested in cytotoxicity study using live cell culture. It was found that the indicator does not affect cells in the study. The results are presented in PIR 84-6 “Safety Testing of Propper Gas-Chex<sup>®</sup> EO Indicator Strips”

### Shelf life and storage conditions:

- Shelf life: 3 years;
- Storage conditions before use: RH: 35-70%, protect from direct light and excessive humidity. Temperature up to 32°C (90°F);
- Storage conditions excursion limits:
  - RH 10-35% - up to 1 month;
  - RH70%-80% - up to 1 week;
  - Temperature 32C-35C – 1 week.
- Storage conditions after use for record keeping: RH: 35-70%, protect from direct light and excessive humidity. Temperature up to 32°C (90°F);

- Record keeping: Gas-Chex<sup>®</sup> indicators strips have stable color change and can be stored for record keeping after processing for years. Excessive humidity or exposure to light may cause some color degradation.

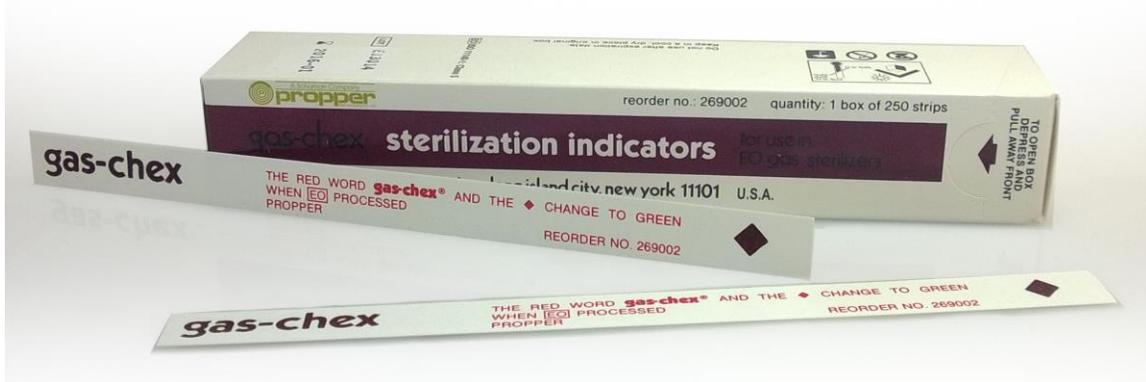
Available products:

26900100 4" (10 cm) Short Gas-Chex<sup>®</sup> indicator strip, 250/box

26900200 8" (20 cm) Gas-Chex<sup>®</sup> indicator strip, 250/box

**8" Gas-Chex<sup>®</sup>** indicator strip has “gas – chex” phrase printed with the indicator ink; it also features a special diamond-shape indicator on the opposite side of the strip. This strip can be used inside larger packages. And opposite parts of the strip represent different areas inside sterilization package.

In some cases the diamond shape indicator can be used as an aid in sterile presentation. The "gas-chex" end of the strip should be placed inside the package, in the area judged to be the most difficult for EO gas to penetrate. The opposite end of the strip with the "diamond" shaped indicator should be positioned in such a way that it becomes visible as soon as the outer wrap is opened. If the "diamond" is not green, sterility is in doubt and to prevent contamination of the sterile area the pack needs to be sent for reprocessing. If the diamond-shaped indicator is green, the strip may be pulled out for examination of “gas-chex” portion of indicator that represents conditions inside the pack. Performance of indicator ink printed as “gas-chex” and in the “diamond” shape is identical.



Pic. 1: 26900100 8” indicator strips.

**4" Short Gas-Chex<sup>®</sup>** indicator is a shorter strip and it does not utilize the "diamond" shaped indicator on the opposite to “gas-chex” side of the strip. In all other respects, it performs the same as the 8" indicator. The indicator is designed to be placed inside sterilization packaging in the area judged to be the most difficult for EO gas to penetrate. It should be examined when the pack is opened.



Pic. 2: 26900200 4” indicator strips.

Instructions for use and typical end-point indicator color change are printed on the product boxes.

Unit of sale: one individual box with 250 strips.