

# Cross-Checks EO

## CI 106

### Indications for Use

The Cross-Checks EO indicators are designed to provide an integrated response to EO gas sterilization in hospital sterilizers. Color change occurs between 30 and 45 minutes exposure to EO gas mixture of 88/12 with gas concentration of 600 mg/L, temperature at 130°F and relative humidity at 45%.

### Color Change

During proper EO sterilization, the check mark at the end of the indicator changes from yellow to brown.

### Stated Values (As determined in an EO sterilization resistometer)

45 minutes at 600 mg/L, 130°F (54°C), >30% R.H.

### Instructions for Use

1. Place a Cross-Checks EO indicator in each pack, peel pouch or tray to be ethylene oxide gas sterilized. For larger packs, place strips at several locations in pack.
2. Sterilize package as recommended by manufacturer.
3. After sterilization is completed, verify that the indicator check mark has changed from yellow to brown.
4. Cross-Checks EO indicator strips must not be used in place of a biological indicator, but can be used in conjunction with a standard infection control monitoring protocol such as that described by the AAMI Standards and Recommended practices: Good Hospital Practice: Sterilization and Sterility Assurance.

### Safety Precautions

- *If there is any doubt about sterility of item, it must be considered NOT sterile*
- *Do not use any strips if the indicator check marks are not yellow in color prior to exposure to EO sterilization processing*

### Storage

- Store at normal room temperature 50° - 100°F (10° – 38°C) and 10-70% R.H. away from oxidizing agents
- No special storage conditions are necessary after exposure to sterilization conditions
- Keep unexposed indicator strips in the sealed bag provided

### Expiry Date

The expiry date is printed on the product packaging. Do not use after expiration date listed on the packaging.

### LOT Number

A unique identification code, [LOT], is printed on each indicator strip and packaging labels.

### Interfering Substances or Conditions

There are no known interfering substances or conditions that could affect the intended use of the indicator or adversely affect the indicator performance.

### Release of Toxic Substances

The indicator releases no known toxic substances in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process.

### Declaration of Conformity

The Cross-Checks EO integrator conforms to all applicable portions ISO 11140-1 pertaining to Type 4 Multicritical Process Variable indicators and FDA requirements for Integrator status.

DF-008 Rev. K



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