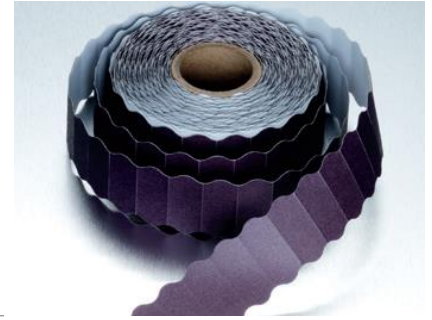


CHEMICAL PROCESS INDICATORS (CPIs) FOR HAND-HELD LABELING SYSTEMS

For Monitoring Ethylene Oxide Sterilization Processes (CLASS 1/TYPE 1)

Crosstex Code: CPI-E02



Product Description

Crosstex Ethylene Oxide (EO) CPIs are manufactured to monitor whether EO exposure conditions were met at the point of application using pressure sensitive adhesive. CPI-E02 are designed for hand-held labeling systems and can accept any ink-based print by hand-held labeling systems. CPI-E02 are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to an EO process and to distinguish between processed and unprocessed units. The indicators color transition from purple to green.

Physical Properties

Process	EO
Dimensions	25 mm x 12 mm Thickness: 0.10 mm (indicator); 0.17 mm (indicator and liner)
Packaging	1,500 Indicators/Roll
Chemical Indicator	Initial Color: Purple Signal Color: Green

Intended Use

The indicators are for use in all EO Sterilization processes.

Class 1/Type 1 Process Indicator Requirements:



- 600 mg/L at 54°C and 60% RH for 20 minutes

Instructions for Use

Use an indicator on each item, pack, peel pouch, or tray intended for EO sterilization. Place at a location considered most challenging for EO gas to reach. Process the packages/items as instructed in the sterilizer validation or manual.

Upon exposure to EO, the indicator will transition from purple to green. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from purple to a shade of green provides indication of exposure to EO. If the signal color is not achieved immediately following exposure, allow the indicator to aerate for 20 minutes. If the signal color is still not achieved, this suggests ideal sterilization conditions may not have been met. Determine if the load was successfully sterilized by examining a biological indicator, or re-sterilize the load using a new chemical indicator.

Performance Characteristics

Result Availability	Immediately following exposure to EO processes
Unexposed*	Exposed to 54°C, 20 minutes, 60% RH, 600 mg/L EO gas*
	

*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.

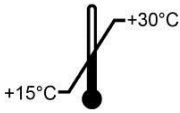






The signal color achieved from exposure to EO may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For a Type 1 Process Indicator, any color change produced during exposure to EO which is different from the initial color is considered acceptable.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators- Part 1: General Requirements

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 70% relative humidity		Keep dry
Shelf life	2 years from the date of manufacture The date of manufacture is based on the day the indicating ink is applied to the substrate. The remaining shelf life upon receipt will be shorter than 2 years		
	Keep away from sterilants. Do not use damaged Indicators or Indicators which have transitioned to green. Do not use after expiration date		

Disposal

Discard as general waste.