



CHEMICAL PROCESS INDICATOR LABEL For Monitoring Steam Sterilization Processes (CLASS / TYPE 1)

Crosstex Code: SIL-1000

Product Description

Crosstex Steam Chemical Process Indicator Labels are designed to aid in distinguishing processed from unprocessed products. The color transition from blue to dark (black/grey) allows end users to easily identify goods which have been exposed in a steam autoclave. The indicators are designed for use in pre-vacuum steam sterilizers operating at 121°C and up to 134°C.

Physical Properties

Process	Steam
Indicator Dimensions	19 mm (0.75" diameter circle)
Imprinted Label Text	"Indicator Label" printed on bottom half of the label
Packaging	1,000 Indicators/Roll
Chemical Indicator	Initial Color: Blue Signal Color: Dark (Black/Grey)

Indications for Use

Class 1 / Type 1 Process Indicator

- 121°C, ≥10 minutes (pre-vacuum)
- 134°C, ≥ 2 minutes (pre-vacuum)



Instructions for Use

Use an indicator on each item, pack, peel pouch, or tray that will be steam sterilized. Place at a location considered most challenging for steam to reach. Process packages/items as instructed in the autoclave/sterilizer validation or manual.

Upon exposure to high temperature steam, the indicator will transition from blue to dark. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from blue to a shade of black/grey provides indication of exposure to high temperature steam. If signal color is not achieved, this suggests ideal sterilization conditions were not met. Determine if the load was successfully sterilized by examining a biological indicator, or re-sterilize the load using a new chemical indicator.

The chemical reaction which causes the color transition is a steam specific reaction.

Performance Characteristics

Result Availability	Immediately following exposure to high temperature steam processes
Unexposed	Exposed to Steam 121°C, 10 minutes
	

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

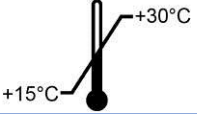






The signal color achieved from exposure to steam may vary from the example above due to differences in processing parameters (i.e. load content, steam quality, cycle time, temperature, etc.).

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	3 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 3 years		
	Keep away from hydrogen peroxide and other sterilants. Storage on top of or near a heat source should be avoided. Do not use damaged Indicators or Indicators which have transitioned to black/grey. Do not use after expiration date		

Disposal

Discard as general waste.