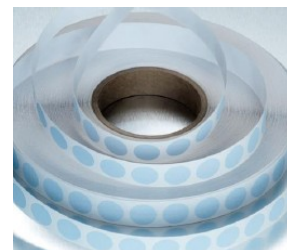




Technical Data Sheet

Chemical Process Indicators (CPIs) For Monitoring Steam Processes ISO 11140-1 TYPE 1

True Indicating Code: CSBP-1



Product Description

True Indicating steam Chemical Process Indicator labels contain no lead or other toxic heavy metals. The Indicators are manufactured to monitor whether exposure conditions were met at the point of placement of the indicator. The indicators are designed for use in steam sterilizers operating at 121°C to 137°C.

Physical Properties

Process	Steam
Dimensions	12 mm (1/2") Dot
Packaging	5,000 Indicators/Roll
Chemical Indicator	Initial Color: Blue Signal Color: Pink

Indications for Use

Type 1 Process Indicator

- 121°C, ≥ 10 minutes
- 134°C, ≥ 2 minutes

Instructions for Use

Use an Indicator on each item, pack, peel pouch, or tray that will be exposed to steam. 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 steam, the Indicator will transition from Blue to Pink. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from Blue to a shade of Pink provides assurance of exposure to steam. A post-exposure color of purple indicates dry exposure conditions and could relate to poor steam quality. If signal color is not achieved, this suggests ideal exposure conditions were not met.

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



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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). A shade of Purple would indicate the presence of poor quality steam.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical indicators- Part 1: General requirements for Type 1 Chemical Process Indicators.

Storage and Shelf Life

	15°C to 30°C		Keep away from Sunlight
	20% to 80% 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 sterilants. Do not use damaged indicators or indicators which have transitioned to Pink. Do not use after expiration date.		

Disposal

Discard as general waste.

