



MULTI-CRITICAL PROCESS VARIABLE INDICATOR For Monitoring Steam Processes ISO 11140-1 TYPE 4

True Indicating Code: CSYN-14



Product Description

True Indicating Multi-critical Process Variable Indicator Strips contain no lead or other toxic heavy metals. The Indicator Strips are intended for use with individual materials (i.e. pouches, pack, Tray) to demonstrate that the material has been exposed to a steam sterilization process to distinguish between processed and unprocessed goods. The indicator strips will transition from an initial Yellow color to a Dark/Black color when exposed to steam.

Physical Properties

Process	Steam
Indicator Strip Dimensions	19 mm x 64 mm (0.75" x 2.5")
Packaging	250 Strips / Pouch
Chemical Indicator	Initial Color: Yellow Signal Color: Dark The word "NOT" will be completely concealed when proper conditions have been met.

Indications for Use

Type 4 Multi-Critical Process Variable Indicator:

- 121°C, 15 minutes
- 134°C, 3.5 minutes

Instructions for Use

Use as a strip or label in each pack, peel pouch or tray intended for steam sterilization. Process packages/items as instructed in the autoclave/sterilizer validation or manual.

Upon exposure to steam, the Indicator will transition from a shade of Yellow to Dark. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from Yellow to Dark and the word "NOT" being completely concealed provides indication of exposure to steam. If the signal color is not achieved this may suggest ideal exposure conditions were not met. Review the exposure conditions and investigate the sterilizer malfunction.

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







Technical Data Sheet

Performance Characteristics

Result Availability	Immediately following exposure to high temperature steam processes
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Unexposed 	Ineffective Exposure 	Exposed to steam 121°C, 15 minutes 
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Colors shown are representations of unexposed, ineffective and exposed signal colors but may vary from actual use.

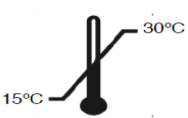






Color Transition is dependent upon load configuration, cycle parameters and may vary. A color transition from the Initial color to a shade of the signal color which results in the word “NOT” being completely concealed is considered an acceptable transition. If the word “NOT” remains visible, check cycle parameters and equipment function.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical indicators- Part 1:General requirements for Type 1 Chemical Process Indicators and Type 4 Multi-critical Process Variable 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 Dark. Do not use after expiration date.		

Disposal

Discard as general waste.

