



CHEMICAL PROCESS INDICATOR LABEL For Monitoring Low-Dose Radiation (Gamma / E-beam) (CLASS 1/TYPE 1)

Crosstex Code: CPI-F01

Product Description

Crosstex Radiation Chemical Process Indicator Labels are manufactured to monitor whether low-dose radiation conditions were met at the point of application using pressure sensitive adhesive. The indicators are designed to demonstrate that exposure to at least 1 kGy of gamma or beta irradiation has occurred.

Physical Properties

Process	Radiation (Gamma and E-beam)
Dimensions	Diameter: 12.7 mm (0.5") circle Thickness: 0.17 mm (indicator); 0.24 mm (indicator and liner)
Packaging	5,000 Indicators/Roll
Chemical Indicator	Initial Color: Green Signal Color: Brown/Violet

Intended Use

Class 1/Type 1 Process Indicator

- 1 kGy







Instructions for Use

Use an indicator on each item, pack, peel pouch, or tray intended for radiation exposure. Process the packages/items as required.

Upon exposure to radiation, the indicator will transition from green to brown/violet. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from green to a shade of brown/violet provides indication of exposure to radiation. If the signal color is not achieved, this suggests ideal conditions were not met. If the load was not successfully processed, re-process the load using a new chemical indicator.

The chemical reaction which causes the color transition from green to brown/violet is a radiation specific reaction and irreversible under most conditions.

Performance Characteristics

Result Availability		Immediately following exposure to radiation			
Unexposed*	UV Light*	1 kGy*	5 kGy*	10 kGy*	25 kGy*
					

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

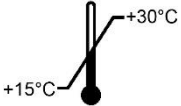

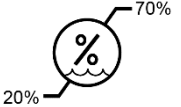




The signal color achieved from exposure to radiation may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, radiation dose, etc.). For a Type 1 Process Indicator, any color change produced during exposure to radiation which is different from the initial 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		Protect from heat and radioactive sources
	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 brown/violet. Do not use after expiration date		

Disposal

Discard as general waste.