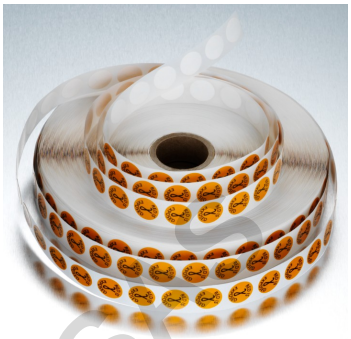
Chemical Process Indicators (CPIs)
For Monitoring Gamma Radiation Processes
ISO 11140-1 TYPE 1



True Indicating Code: CRYR-3
Code DUTSCHER : **633351**

Product Description

True Indicating Radiation Chemical Process Indicator labels contain no lead or other toxic heavy metals. The Indicators are manufactured to monitor whether radiation conditions were met at the point of application. The Indicators are designed using a latex-free pressure sensitive adhesive and are for use with radiation operating as low as 10 kGy, with optimal color transition at dose levels of 25 kGy.

Physical Properties

Process	Gamma Radiation
Dimensions	12 mm (1/2") Dot
Label Text	"Red is γ Exposed"
Packaging	5,000 Indicators/Roll
Chemical Indicator	Initial Color: Yellow Signal Color: Red

Indications for Use

Type 1 Process Indicator

- 10 kGy minimum dose level per ISO 11140-1:2014 Sterilization of health care products—Chemical indicators Part 1: General requirements
- 25 kGy typical dose level; Indicators may be used for higher dose levels. The higher the dose of exposure a the darker red the transition color will become.

Instructions for Use

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

Upon exposure to radiation, the Indicator will transition from Yellow to Red. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from Yellow to a shade of Dark Orange/Red provides indication of exposure to radiation. The longer the dose of radiation, the deeper the signal color will become. If 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 Indicator.

The chemical reaction which causes the color transition is a radiation specific reaction and is irreversible under most conditions. Post exposure storage near pH basic environments such as reagents or cleaning product fumes may cause involuntary reversion from red back to Yellow/Orange.

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Performance Characteristics

Result Availability	Immediately following exposure to radiation

Unexposed	1 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, a color change to shade of Orange/Red 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 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 Red. Do not use after expiration date.		

Disposal

Discard as general waste.

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