



Technical Data Sheet

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

True Indicating Code: CRYR-5



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 using latex-free pressure sensitive adhesive. The Indicators are designed for use with radiation operating as low as 10 kGy.

Physical Properties

Process	E-beam Radiation
Dimensions	14 mm x 14mm Squares
Packaging	5,000 Indicators/Roll
Chemical Indicator	Initial Color: Yellow Signal Color: Red

Indications for Use

Type 1 Process Indicator

- 10 kGy

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 Dark Orange/Red provides indication of exposure to radiation. The longer the dose level, the deeper the signal color. 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 chemical indicator.

The chemical reaction which causes the color transition is an e-beam 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.



TRUE INDICATING
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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, e-beam 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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