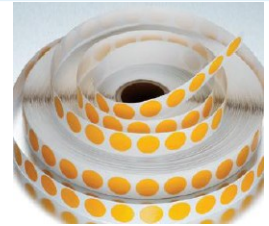


Chemical Process Indicators (CPIs) For monitoring Radiation (Gamma / E-beam) (CLASS / TYPE 1)

Excelsior Code: CPI-R01E



Product Description

Excelsior 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	Radiation (Gamma and E-beam)
Dimensions	12.7 mm (1/2") Dot
Packaging	5,000 Indicators/Roll
Chemical Indicator	Initial Colour: Yellow Signal Colour: Red Chemical Indicator inks contain no lead or other toxic heavy metals

Indications for Use

Class 1 / 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 colour may vary depending on the load configuration, length and conditions of exposure. A colour transition from yellow to red provides indication of exposure to radiation. If signal colour 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 colour 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.

Performance Characteristics

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

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

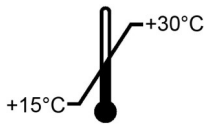






The signal colour achieved from exposure to radiation may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, radiation dose etc.) For a Type 1 Process indicator, a colour change to shade of orange/red produced during exposure to radiation which is different from the initial colour 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.