

# RADIATION CHEMICAL PROCESS INDICATORS

- Compliance** - Indicators meet ISO 11140-1 for Class 1 Process Indicators.
- User Friendly** - Non-toxic, self adhesive, yellow to red transition
- Convenient** - Room temperature for storage  
24 month shelf life
- Reliable quality** - Each lot is tested to verify color transition.




NAMSA Radiation Chemical Process Indicators (CPIs) are manufactured to meet performance specifications described in ISO 11140-1 "Sterilization of health care products - Chemical indicators - Part 1: General Requirements," for Class 1 Process Indicators. The yellow-to-red color transition is dose dependent (see chart to the right). NAMSA Radiation CPIs are not intended for use as dosimeters, but rather as throughput process indicators used to monitor exposure to the radiation process. NAMSA Radiation CPIs are intended for use in gamma or e-beam radiation sterilization processes only.







## PRODUCT SPECIFICATIONS AND APPLICATIONS

NAMSA Radiation CPIs are labeled with 24 months of shelf life and room temperature storage. The shelf life is based on the date the indicating ink is applied to the substrate. Product may have a shelf life of less than 24 months at the time of purchase. Moderate heat (up to 35°C) will not adversely affect indicators performance. Labeled storage conditions should be observed at all times to maintain optimum sensitivity. Avoid contact or storage of indicators near substrates which are acidic or basic in nature, such as cleaning solutions and disinfectants.

Exposed indicators are stable and remain red when stored under labeled conditions. Each roll is individually packaged with a certificate of conformance to ensure the products' quality and consistency.

NAMSA Radiation CPIs are non-odorous and non-hazardous to use. The printed labels are safe to dispose in general waste receptacles. No MSDS required per CFR.1910.1200.

Product Type	Number of indicators per roll	Product Code	Example
Plain 1/2" (12.7 mm) circles	5,000	CPI-R01	
Meto® gun indicators for hand-held labeling systems	1,000	CPI-R02	
Imprinted 1/2" (12.7 mm) circles Text: "Red Is Exposed"	5,000	CPI-R03	

Product Color Change Performance <sup>1</sup> NAMSA Radiation Chemical Process Indicators			
Product CPI-R01			
Unexposed		10 kGy <sup>4</sup>	
UV Light <sup>2</sup> 20 minutes		15 kGy	
1 kGy <sup>3</sup>		25 kGy	

<sup>1</sup> Samples are representative of performance according to ISO 11140-1 for Class 1 Process Indicators.  
<sup>2</sup> The ultraviolet radiation that is designed to show the indicator does not change color when exposed to non-ionizing radiation such as sunlight.  
<sup>3</sup> No change or a change that is markedly different from the visible change to red is expected after exposure to a dose level of 1 kGy.  
<sup>4</sup> A markedly different color (similar to Pantone® 173 C) is expected after exposure to a dose level of 10 kGy. The red endpoint color will darken with increased dose levels.

*NAMSA offers a variety of sterilization monitoring products and the full range of pre-clinical safety testing and consulting services to medical device, pharmaceutical and biotech companies throughout the world.*

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