

STEAM CHEMICAL PROCESS INDICATORS

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


NAMSA Steam 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 blue-to-pink color transition is sensitive to time, temperature and the presence of saturated steam (see chart to right). NAMSA Steam CPIs are not intended for use as dosimeters, but rather as throughput process indicators used to monitor exposure to the steam sterilization process.







PRODUCT SPECIFICATIONS AND APPLICATIONS

NAMSA Steam 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. Labeled storage conditions should be observed at all times to maintain optimum sensitivity.

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

NAMSA Steam CPIs are manufactured using a water-based ink formulation made without the use of any heavy metals. They are nonodorous and nonhazardous 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-S01	

Product Color Change Performance ¹ NAMSA Steam Chemical Process Indicators			
Product CPI-S01			
Unexposed		Dry Heat ² 140°C 30 minutes	
Saturated Steam ³ 121°C 3 minutes		Saturated Steam ³ 134°C 0.5 minutes	
Saturated Steam ⁴ 121°C 10 minutes		Saturated Steam ⁴ 134°C 2 minutes	

¹ Samples are representative of performance according to ISO 11140-1, for Class 1 Process Indicators.
² After exposure to a dry heat process at 140°C for 30 minutes, the indicator shall show either no change or a change that is markedly different from the change occurring after exposure to a steam process.
³ After exposure to shortened steam cycles, a change to pink similar to Pantone® 677 C or lighter can be expected.
⁴ After exposure to a steam sterilization process, an endpoint color of pink similar to Pantone® 684 C or darker can be expected.

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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