

## CHEMICAL PROCESS INDICATORS (CPIs) For Monitoring Depyrogenation Processes

Crosstex Code: CPI-DP1



### Product Description

CPI-DP1 are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to a high temperature dry heat or depyrogenation process and to distinguish between processed and unprocessed units. The indicators color transition from pink to dark, either violet or brown depending on the exposure conditions.

### Physical Properties

|                    |  |
|--------------------|--|
| Process            | Depyrogenation   |
| Dimensions         | Diameter: 12.7 mm (0.5") circle<br>Thickness: 0.10 mm (indicator); 0.17 mm (indicator and liner) |
| Packaging          | 500 Indicators/Roll  |
| Chemical Indicator | Initial Color: Pink<br>Signal Color: Violet/Brown  |

### Intended Use

The indicators are for use in depyrogenation systems operating at up to 250°C for a maximum of 60 minutes.




- ≤250°C for up to 60 minutes

### Instructions for Use

Use an indicator on each item that will be depyrogenated. Process the packages/items as instructed in the oven validation or manual.

Upon exposure to dry heat, the indicator will transition from pink to violet/brown. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from pink to a shade of violet/brown provides indication of exposure to high temperature dry heat or a depyrogenation process.

## Performance Characteristics

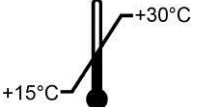

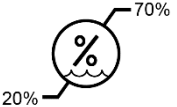


|   |   |   |
|---|---|---|
| Result Availability   | Immediately following exposure to high temperature dry heat or depyrogenation processes |   |
| Unexposed*  | Exposed to 160°C, 40 minutes*   |  |
|   | Exposed to 250°C, 60 minutes*   |  |
|  |   |   |

\*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.



The signal color achieved from exposure to depyrogenation may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). Any color change produced during exposure to high temperature dry heat which is different from the initial color is considered acceptable.

## Storage and Shelf Life

|   |  |  |                         |
|---|--|--|-------------------------|
|  | 15°C to 30°C   |  | Keep away from sunlight |
|  | 20% to 70% relative humidity   |  | Keep dry                |
| <b>Shelf life</b>   | 2 years from the date of manufacture<br>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 2 years |  |                         |
|  | Keep away from sterilants. Do not use damaged Indicators or Indicators which have transitioned to green. Do not use after expiration date  |  |                         |

## Disposal

Discard as general waste.