



Technical Data Sheet

Chemical Process Indicators (CPIs) For Monitoring Dry Heat or Depyrogenation Processes ISO 11140-1 TYPE 1

Product Code: CDBN-1



Product Description

True Indicating Dry Heat Chemical Process Indicator labels contain no lead or other toxic heavy metals.

CDBN-1 are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to high temperature dry heat and to distinguish between processed and unprocessed units. The Indicators transition color from Blue to Dark Gray (Dry Heat) or Black (Depyrogenation).

Physical Properties

Process	Dry Heat or Depyrogenation
Dimensions	12.7 mm (0.5") Dot
Packaging	5,000 Indicators/Roll
Chemical Indicator	Initial Color: Blue Signal Color (dry heat) : Dark Grey Signal Color (depyrogenation) : Black

Indications for Use

The indicators are used in high temperature dry heat sterilizers operating at 160°C or depyrogenation ovens operating up to 250°C

Type 1 Process Indicator Requirements for Dry Heat:

- 160°C for 40 minutes

Instructions for Use

Use an Indicator on each item, pack, peel pouch, or tray that will be processed by dry heat. Place at a location considered most challenging for dry heat to reach. Process packages/items as instructed in the sterilizer validation or manual.

Upon exposure to dry heat, the indicator will transition from Blue to Dark Gray then to Black. The transition color may vary depending on the load configuration, length and temperature of exposure. A color transition from Blue to a shade of Gray/Black provides indication of exposure to dry heat. If the signal color is not achieved this may suggest ideal exposure conditions were not met. Review the exposure conditions and investigate the sterilizer for malfunction.

The chemical reaction which occurs upon exposure to dry heat causing the color transition from Blue to Dark is irreversible.



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Performance Characteristics

Result Availability	Immediately following exposure to dry heat processes
	Exposed to 160°C, 40 minutes
	Exposed to 250°C, 30 minutes
	

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



The signal color achieved from exposure may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature etc.) For a Type 1 Process indicator for dry heat, a color change to a shade of Gray/Black produced during exposure is considered acceptable.

Storage and Shelf Life

	15°C to 30°C		Keep away from Sunlight
	20% to 80% Relative Humidity		Keep Dry
Shelf Life	4 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 4 years.		
	Keep away from sterilants. Do not use damaged indicators or indicators which have already transitioned. Do not use after expiration date.		

Disposal

Discard as general waste.

