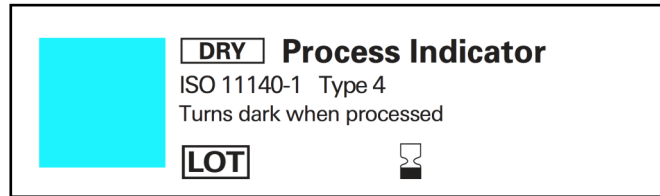




MULTI-CRITICAL PROCESS VARIABLE INDICATOR STRIP – LABEL For Monitoring Dry Heat Processes ISO 11140-1 TYPE 4

True Indicating Code: CDBN-14



Product Description

True Indicating Multi-critical Process Variable Indicator Strips contain no lead or other toxic heavy metals. The Indicator strips are manufactured to monitor whether dry heat has penetrated to the point of placement of the strip within a pouch, instrument wraps, or applied as a label to other items requiring dry heat sterilization by reacting two critical process variables (time and temperature). Internal chemical indicators should be used inside each pack to be processed.

Physical Properties

Process	Dry Heat
Indicator Strip Dimensions	19 mm x 70 mm (0.75" x 2.75")
Packaging	250 Strips / Pouch
Chemical Indicator	Initial Color: Blue Signal Color: Dark Gray

Indications for Use

Type 4 Process Indicator Requirements:

- 160°C, 40 minutes

Instructions for Use

Use a strip in each pack, peel pouch, tray or label other items to be processed by dry heat. 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. The transition color may vary depending on the load configuration, length and conditions of exposure. The higher the temperature, the darker the signal color will become. A color transition from Blue to Dark 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.

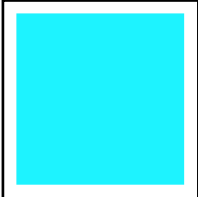

The chemical reaction which occurs upon exposure to dry heat causing the color transition from Blue to Dark is irreversible.





Technical Data Sheet

Performance Characteristics

Result Availability	Immediately following exposure to dry heat
Unexposed	Exposed to dry heat 160°C, 40 minutes
	

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

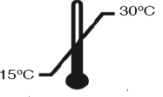
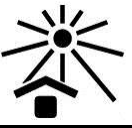





The signal color achieved from exposure to dry heat may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For Type 4 Multi-critical Process Variable Indicators, a color change to Dark Gray/Black, is an indication that all process variables were achieved during exposure to dry heat.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical indicators- Part 1:General requirements For Type 1 Process Indicators & Type 4 Multicritical process Variable 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 already transitioned. Do not use after expiration date.		

Disposal

Discard as general waste.

