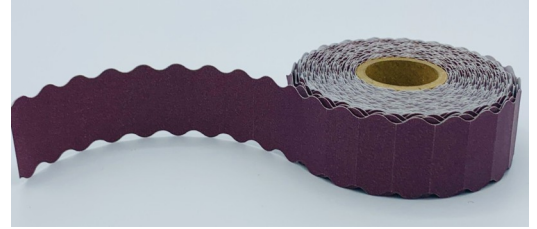




Technical Data Sheet

Chemical Process Indicators (CPIs) For Hand Held Labelling Systems (METO) For Monitoring Ethylene Oxide Processes ISO 11140-1 TYPE 1



True Indicating Code: CEVG-2

Product Description

True Indicating Ethylene Oxide (EO) CPIs contain no lead or other toxic heavy metals. The Indicators are manufactured to monitor whether EO conditions were met at the point of application using pressure sensitive adhesive. The Indicators are designed for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to an EO process and to distinguish between processed and unprocessed units. The indicators transition from Violet to Green.

Physical Properties

Process	EO
Dimensions	25 mm x 12 mm (1" x 0.5") METO Thickness: 0.10mm (indicator); 0.17mm (indicator and liner)
Packaging	1,500 Indicators/Roll
Chemical Indicator	Initial Color: Violet Signal Color: Green

Indications for Use

The Indicators are for use in all EO sterilization processes.

Type 1 Process Indicator requirements:

- 600 mg/L at 54°C and 60% RH for 20 minutes

Instructions for Use

Use an Indicator on each item, pack, peel pouch, or tray intended for EO sterilization. Place at a location considered most challenging for EO gas to reach. Process the packages/items as instructed in the sterilizer validation or manual.

Upon exposure to EO, the Indicator will transition from Violet to Green. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from Violet to a shade of Green provides indication of exposure to EO. If the signal color is not achieved, this suggests ideal exposure conditions may have not been met. Determine if the load was successfully processed by examining a biological indicator, or re-process the load using a new chemical indicator.

The chemical reaction which causes the color transition is an EO specific reaction and is irreversible under most conditions. Post exposure storage near acidic environments such as reagent or cleaning product fumes may cause involuntary reversion from Green back to Violet/Brown.



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Performance Characteristics

Result Availability	Immediately following exposure to EO Processes
Unexposed	Exposed to 54°C, 20 mins, 60% RH, 600 mg/L EO gas
	

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



The signal color achieved from exposure to EO 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, a color change to a shade of Green produced during exposure is considered acceptable.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators- Part 1:General Requirements for Type 1 Chemical Process 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 transitioned to green. Do not use after expiration date.		

Disposal

Discard as general waste.

