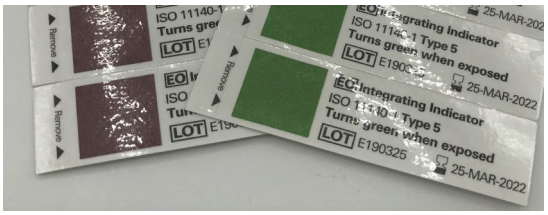
Technical Data Sheet

INTEGRATING INDICATOR STRIP - LABEL
For Monitoring Ethylene Oxide Processes
ISO 11140-1 TYPE 5

True Indicating Code: CEVG-15



Product Description

True Indicating Integrating Indicator Strips contain no lead or other toxic heavy metals. The Indicator Strips are intended for use with individual materials (i.e. packs, containers) to demonstrate that the material has been sterilized by an EO process. Integrating Indicators react to all critical process variables (time, temperature, relative humidity and EO gas concentration) and are equivalent to, or exceed, the performance requirements given in ISO 11138 – series for BIs. The backing of the strip is removable which exposes latex-free adhesive for easy application of the strip to packages during exposure and /or for record keeping purposes after exposure.

Physical Properties

Process	EO
Indicator Strip Dimensions	19 mm x 70 mm (0.75” x 2.75”)
Packaging	250 Strips / Package
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 Stated Value: 600mg/L at 54°C and 60% RH for 20 minutes

Type 5 Integrating Indicator Stated Value: 600 mg/L at 54°C and 60% RH for 40 minutes or 600 mg/L at 37°C and 60% RH for 75 minutes

Instructions for Use

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

Upon exposure to EO, the Integrating Indicator will transition from a 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 a bright green signal color is not achieved this may suggest ideal conditions were not met. Review the exposure conditions and investigate the sterilizer malfunction.

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 to Violet/Brown.

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Performance Characteristics

Result Availability	Immediately following exposure to EO
Unexposed	Exposed to 600mg/L at 54°C & 60% RH for 40 mins or at 37°C & 60% RH for 75 mins

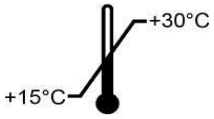
Colors shown are representative of printed ink initial and signal color but may vary from the actual use.

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 Type 5 Integrating Indicators, a color change to Bright Green, is an indication that all process variables were achieved during exposure to EO.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical indicators- Part 1:General requirements for Type 5 Integrating 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 after expiration date. Do not use the product is the Indicator has transitioned prior to use.		

Disposal
Discard as general waste.

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