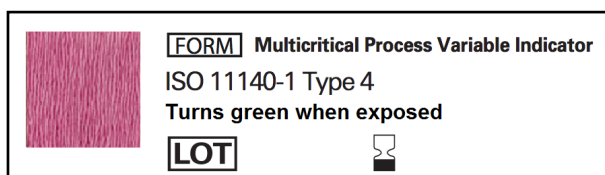


CHEMICAL PROCESS INDICATOR STRIP

For Monitoring Steam Formaldehyde Sterilisation Processes (CLASS / TYPE 4)

Excelsior Code: CH20-250E



Product Description

Excelsior Multicritical Process Variable 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 exposed to a steam formaldehyde process to distinguish between processed and unprocessed items. Multicritical Process Variable Indicators react to all critical process variables (time, temperature, and steam formaldehyde concentration). 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	steam formaldehyde
Indicator Strip Dimensions	19 mm x 70 mm (0.75" x 2.75")
Packaging	250 Strips / Package
Chemical Indicator	Initial Colour: Pink Signal Colour: Green Chemical Indicator Inks contain no lead or other toxic heavy metals

Indications for Use

Class /Type 1 Process Indicator Requirements:

- $\geq 70^{\circ}\text{C}$, ≥ 15 mins, ≥ 1.0 M Steam Formaldehyde

Class /Type 4 Process Indicator Requirements:

- $\geq 70^{\circ}\text{C}$, ≥ 15 mins, ≥ 1.0 M Steam Formaldehyde

Instructions for Use

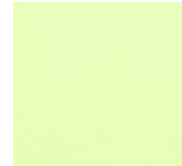
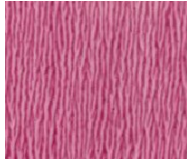
Use a strip or label in each pack, peel pouch or tray to be exposed. Process packages/items as instructed in the steriliser validation or manual.

Upon exposure to steam formaldehyde, the chemical indicator will transition from a shade of pink to green. The transition colour may vary depending on the load configuration, length and conditions of exposure. A colour transition from a shade of pink to green provides indication of exposure to steam formaldehyde. If the signal colour is not achieved this may suggest ideal exposure conditions were not met. Review the exposure conditions and investigate the steriliser malfunction.

The Chemical reaction is irreversible.

Performance Characteristics

Result Availability	Immediately following exposure to steam formaldehyde
Unexposed*	Exposed to 1M steam formaldehyde 70°C, 15 minutes*



*Colours shown are representations of printed ink initial signal colours but may vary from actual use.



The signal colour achieved from exposure to steam formaldehyde may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For Type 4 Multicritical Process Variable Indicators, a colour change to green, is an indication that all process variables were achieved during exposure to steam formaldehyde.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators- Part 1:General Requirements For Type 1 chemical 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		Do not reuse
	Keep away from sterilants. Do not use after expiration date. Do not use the product if the indicator has transitioned prior to use.		

Disposal

Discard as general waste.