

MULTICRITICAL PROCESS VARIABLE INDICATOR STRIP

For Monitoring Steam Sterilisation Processes (CLASS / TYPE 4)

Excelsior Code: TST-4SE



Product Description

Excelsior multi critical process variable indicator strips contain no lead or other toxic heavy metals. The Indicator strips are intended for use with individual materials (i.e pouches, pack. Tray) to demonstrate that the material has been exposed to a steam sterilisation process to distinguish between processed and un-processed goods. The indicator strips will transition from an initial yellow colour to a dark/black colour when exposed to high temperature steam.

Physical Properties

Process	Steam
Indicator Strip Dimensions	19 mm x 64 mm (0.75" x 2.5")
Packaging	100 Strips / Package
Chemical Indicator	Initial Colour: Yellow Signal Colour: Dark Chemical Indicator Inks contain no lead or other toxic heavy metals

Indications for Use

- 121°C, 15 minutes
- 134°C, 3.5 minutes

Instructions for Use

Use as a strip or label in each pack, peel pouch or tray intended for steam sterilisation. Process packages/ items as instructed in the autoclave/steriliser validation or manual.

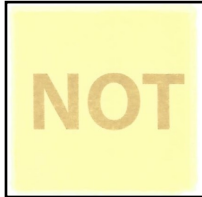
Upon exposure to high temperature steam, the chemical indicator will transition from a shade of yellow to dark. The transition colour may vary depending on the load configuration, length and conditions of exposure. A colour transition from yellow to dark provides indication of exposure to high temperature steam. 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 which causes the colour transition is a steam specific reaction and is irreversible.

Performance Characteristics

Result Availability	Immediately following exposure to high temperature steam processes
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Unexposed*	Exposed to steam 121°C, 15 minutes
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*Colours shown are representations of printed ink initial and signal colours but may vary from actual use.



Colour Transition is dependent upon load configuration, cycle parameters and may vary. A colour transition from the Initial colour to a shade of the signal colour which results in the word "NOT" being completely concealed is considered an acceptable transition. If the word "NOT" remains visible, check cycle parameters and equipment function.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators- Part 1:General Requirements for Type 1 Chemical Process Indicators & Type 4 Multi-critical Process Variable Indicators.

Storage and Shelf Life Disposal

	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.		

Discard as general waste.