



MULTICRITICAL PROCESS VARIABLE INDICATOR STRIP For Monitoring Steam Sterilisation Processes (CLASS / TYPE 4)

Rodwell Part No. AC981 (885-0302)

OEM 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 unprocessed 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	19mm x 64mm
Packaging	100 Strips / Package
Chemical Indicator	Initial Colour: Yellow Signal Colour: Dark Brown / Black Chemical Indicator Inks contain no lead or other toxic heavy metals

Indications for Use

Type 4 Multi-critical Process Variable Indicator :

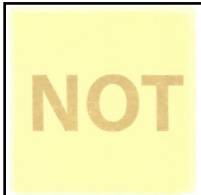

- 121°C, 15 minutes
- 134°C, 3 minutes

Instructions for Use

Use a strip 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 yellow to dark brown / black. The transition colour may vary depending on the load configuration, length and conditions of exposure. A colour transition from yellow to a shade of dark brown or black 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.

Result Availability	Immediately following exposure to high temperature steam process
Unexposed	Exposed to steam 121°C, 15 minutes
	

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

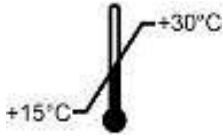



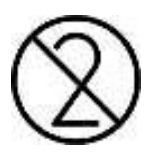



The signal colour achieved from exposure to steam may vary from the example above due to differences in processing parameters (i.e. load content, steam quality, cycle time, temperature, etc.).

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

	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		Don not reuse
	Keep away from sterilants. Do not use after expiration date.		

Disposal

Discard as general waste.