

TECHNICAL DATA SHEET

EO AUTOCLAVE TAPE

- PRODUCT CODE** : **ATE1950 – ATE2550**
- RELATED STANDARDS** : PMSSteriTest EO Indicator Printed Autoclave Tape is classified as Type 1 according to ISO 11140-1 standard. CE marking is not applicable for indicator products, because this product is not considered as medical device under the clause of the Medical Device Regulation (EU) 2017/745.
- INTENDED USE** : EO Indicator Autoclave Tapes are used to close wraps of the medical devices to be sterilized and provide visual confirmation that the package has been processed in a EO sterilization.
- OPERATION CONDITIONS** : PMSSteriTest EO Autoclave Tape are designed operate %60±%10 humidity, 37°C±0,5°C, 90 min or 54°C±0,5°C 30 min at 600±30 mgrating/L EO concentration.
- CHEMICAL COMPOSITION** : The sterilization indicator used in printing is water based and contains following components

Liquid (Water+other additives)	58%
Solid	42%

Before Sterilization



After Sterilization



The Ethylene Oxide Autoclave Tape is not classified as dangerous.

- PRODUCT SPECIFICATIONS** : 19 mm x 50 m or 25 mm x 50 m size, EO indicator printed and lacquer covered paper tape. The adhesive used is Hot Melt Type.

AUTOCLAVE TAPE	SPEIFICATION	UNIT	STANDARD	TYPICAL VALUE
AUTOCLAVE TAPE	WIDTH	mm	-	19±1
				25±1
	LENGTH	m	-	50± % 1
	THICKNESS	µm	-	100 ± 5
	ADHESIVE	g/m ²	-	35 ±3
	INSTANT TACK	N/19 mm	ASTM D 3121	Min.1.0
	PEEL ADHESION	N/19 mm	ASTM D 3121	Min.1.3
	INDICATOR CONTROL	-	ISO 11140-1	Must return the specified color

- PACKAGING** : Inner Packaging : Each product is wrapped with polyester packaging.
Outer Packaging: 19x50, 60 pieces in carton box
25x50, 36 pieces in carton box



PMSSteriTest™