



TECHNICAL DATA SHEET

ADHESIVE INDICATOR LABEL FOR ETO STERILIZATION

- PRODUCT CODE** : **IL1002**
- RELATED STANDARDS** : PMSSteriTest EO Indicator Label 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** : PMSSteriTest EO Indicator Labels provide visual confirmation that the package has been processed in a ETO sterilizer. PMS Steri-test Indicator labels can be printed with traceability providing data like sterilization/expiry date, autoclave and cycle no.
- OPERATION CONDITIONS** : EO Indicator Labels are designed operate %60±: %10 humidity, 37°C±0,5°C, 90 min or 54°C±0,5°C 30 min at 600±30 mg/L EO concentration.
- | <u>Before Sterilization</u> | <u>After Sterilization</u> |
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- CHEMICAL COMPOSITION** : The sterilization indicator ink used for printing contains following components in ppm levels.
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|--------------------------------|-----|
| Liquid (Water+other additives) | 58% |
| Solid | 42% |
- PRODUCT SPECIFICATIONS** : Contains no substance classified as hazardous, which should be taken into account according to EC directives. PMSSteriTest adhesive indicator labels are double sided self-adhesive labels available with chemical indicator for steam sterilization method. Each roll contains 750 pieces indicator printed labels having size 28 mm x 28 mm. The indicator is printed as rectangle. Traceability data, sterilization/expiry date, autoclave /cycle no., can be printed on label by using PMS label gun
- PACKAGING** : 750 Labels per roll



PMSSteriTest™