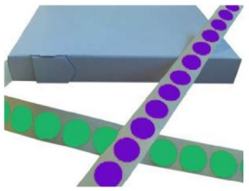
GAMMATEX™

Chemical Sterilisation Indicators

Technical Data Sheet : Product Code: 12ETO

- Chemical Process Indicators (CPIs)
- For Monitoring Ethylene Oxide Processes
- ISO 11140-1 TYPE 1



Product Code	Packing Specification	Unexposed	Exposed to 54ºC, 20 mins, 60% RH, 600 mg/L
12ETO	12mm plain dots (unprinted) Supplied in rolls of 5,000 labels Supplied in cardboard dispenser cartons		

The colour change achieved from exposure to EO may vary from the example above due to differences in processing parameters (i.e. dosage level, plant load content, process cycle timings). For a Type 1 Process indiciator a colour change to a shade of green after exposure is deamed acceptable.

Product Description:

12ETO Gammatex Ethylene Oxide (ETO) Chemical Process Indicator labels are self adhesive labels that undergo a simple colour change when exposed to the Ethylene Oxide (ETO) sterilisation process. The labels undergo a clear and distinct colour change from purple to green when activated. Gammatex Ethylene Oxide (ETO) Chemical Process Indicator labels can be used as process indicators to easily identify processed and unprocessed products and are designed to be qualitative indicators and not quantitative dosimeters for the Ethylene Oxide (ETO) sterilisation process. Gammatex Ethylene Oxide (ETO) Chemical Process Indicator labels may be used to sterilise medical and pharmaceutical products that cannot support conventional high temperature steam sterilization - such as devices that incorporate electronic components, plastic packaging or plastic containers. Processed labels may be retained as part of the quality control record for validation purposes. Gammatex Ethylene Oxide (ETO) Chemical Process Indicator labels contain no lead or other toxic heavy metals and only use latex-free pressure sensitive adhesive.

Supply unit:

12ETO Gammatex Ethylene Oxide (ETO) Chemical Process Indicator labels are available in standard reel sizes of 5,000 labels and packed in dispenser cartons. Although the reel size can be tailored to individual requirements - please contact us for more details

Application:

Gammatex Ethylene Oxide (ETO) Chemical Process Indicator labels should be removed from the backing paper and applied to a clean, dry patch of the article to be processed with the coloured surface uppermost. The label should be subject to the full process cycle. When processing conditions vary then a representative number of labels should be applied. The label should not be used for more than one processing cycle.

Shelf life and storage:

The shelf life of 12 months is recommended for both unprocessed and processed labels provided they are stored in ambient conditions below 20°C and 50% R.H. and in the dark. Unprocessed indicators may experience colour changes at raised temperatures. Unprocessed labels may be experience colour changes at elevated temperatures or under high humidity conditions. The indicators must be protected from exposure to UV light, sunlight, excessive heat, chemicals or chemical vapours.

Disposal:

Gammatex Ethylene Oxide (ETO) Chemical Process Indicator labels may be disposed of using customary practice for non-hazardous materials. No special precautions are required. Please follow any relevant environmental legislation

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