

# GAMMATEX™

## Chemical Sterilisation Indicators

### Technical Data Sheet : Product Code: GAMMASTRIPE

- Chemical Process Indicators (CPIs)
- For Monitoring Radiation (Gamma or E-beam)
- ISO 11140-1 TYPE 1



| Product Code  | Packing Specification   | Unexposed | Exposed- 1 kGy | Exposed- 10 kGy | Exposed- 25+ kGy |
|---|---|-----------|----------------|-----------------|------------------|
| GAMMA STRIPE  | Label size - <i>MADE TO ORDER</i><br>Labels per roll - <i>MADE TO ORDER</i><br>Suitable for either Thermal Transfer or Direct Thermal overprint |           |                |                 |                  |
| The colour change achieved from exposure to radiation can vary from the samples shown above due to differences in the parameters of the processing (i.e. dosage level, plant load content, process cycle timings) For a Type 1 Process indicator, a color change to a shade of Orange/Red after the exposure process, which is significantly different from the initial color is deemed acceptable. |   |           |                |                 |                  |

### Product Description:

GAMMASTRIPE Gammatex Radiation Chemical Process Indicator labels are self adhesive labels that undergo a simple colour change when exposed to Gamma or E-Beam radiation. The labels undergo a clear and distinct colour change from yellow to red when activated. Gammatex Radiation 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 Gamma or E-Beam irradiation sterilisation process. Gammatex Radiation Chemical Process Indicator labels may be used in such applications as food irradiation and in medical and surgical applications. Processed labels may be retained as part of the quality control record for validation purposes.

Each batch of Gammatex Radiation Chemical Process Indicator labels is independently validated in a leading UK sterilisation facility prior to conversion into final product. Gammatex Radiation Chemical Process Indicator labels contain no lead or other toxic heavy metals and only use latex-free pressure sensitive adhesive. Gammatex Radiation Chemical Process Indicator labels are designed for use with radiation sterilisation operating as low as 10 kGy.

### Supply unit:

GAMMASTRIPE Gammatex Radiation Chemical Process Indicator labels are made to order and therefore can be made to suit any end users specific specifications. The GAMMASTRIPE Gammatex Radiation Chemical Process Indicator labels are manufactured with a base blank label with an integrated gamma stripe along its edge. The base label can be made using materials suitable for either Thermal Transfer or Direct Thermal over printing by the end users. This facility allows the end user to over print marketing material, branding, serial numbers, LOT or batch information. Label size, Base material and reel sizes can be tailored to individual requirements - please contact us for more details.

### Application:

Gammatex Radiation 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 24 months is recommended for both unprocessed and processed labels provided the labels are stored in a dark, cool location at temperatures between 2° and 22°C or 35° and 72°F. 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. After exposure, if products are placed near pH basic environments such as reagents or cleaning products the vapours can create reversion of the label colours from Red back to Yellow/Orange.

### Disposal:

Gammatex Radiation 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.

**The data contained in this application is based upon careful investigations and is intended for guidance only. Users are advised to carry out their own tests as to the suitability of the products for a particular use. Gammatex do not accept responsibility for uses of its products that are not under its control.**