

GENERAL INFORMATION SHEET IRRAD STERILIZATION PROCESS INDICATORS

Description:

Etigam BV Irrad sterilization process indicators are radiation sensitive labels which show a significant colour change from yellow (unexposed) to red (exposed: dosage range >10 kGy), when exposed to Gamma, X-ray or Electron beam radiation. The sensitive version shows a significant colour change from green (unexposed) to violet (exposed: dosage range > 6 kGy), The colour change of the indicators is dose dependent.

Etigam BV Irrad sterilization process indicators are intended for use with individual units (e.g. packs, containers) to identify processed and unprocessed units. The sterilization process indicators manufactured by Etigam BV are not considered to be a medical device and therefore any regulation for medical devices does not apply to Etigam's sterilization process indicators.

Etigam BV Irrad sterilization process indicators are pressure-sensitive indicators and the degree of bond is influenced by the pressure which is used to apply the adhesive to the surface. Furthermore surface factors such as smoothness, surface energy, removal of contaminants, etc. are also important to proper bonding.

Etigam BV Irrad sterilization process indicators are Type 1 indicators and are manufactured in compliance with ISO 11140-1:2014 "Sterilization of health care products -Chemical indicators- Part 1: General requirements".

Etigam BV holds the ISO 9001 quality management certificate. A copy of this certificate can be downloaded on the website www.etigam.nl

Quality control:

During and after the production process the sterilization process indicators undergo several quality checks. Samples of each batch are exposed to gamma radiation at an external facility with an average dose of:

- 5 kGy (0.5 Mrad: only green to violet)
- 10 kGy (1.0 Mrad)
- 15 kGy (1.5 Mrad)
- 25 kGy (2.5 Mrad)

Recommended storage conditions: (Before and after exposure)

The sterilization process indicators must be stored dark and cool, between 2 and 22°C (35°F and 72°F).

Shelf life:

The expiry date of sterilization process indicators is 24 months after date of production, when stored under proper conditions.

Instructions for use:

- Sterilization process indicators may not perform properly unless stored under proper conditions as stated on the package label.
- Sterilization process indicators must be protected from exposure to excessive daylight and heat, chemicals, chemical vapours and liquids.
- Exposed gamma / E-beam sterilization process indicators are sensitive to ethylene oxide and may undergo colour reversion in its presence.
- Contact between medical devices and sterilization process indicators must be prevented.
- Chemical by-products formed by irradiation of medical devices and packaging materials may interfere with proper colour development.
- Contact between the sterilization process indicators and material containing plasticizers may cause effect on the performance of the sterilization process indicators.
- Sterilization process indicators are no dosimeters. Colour change of the sterilization process indicators indicates exposure to the process. The process itself needs to be validated in order to assure the sterility of the products.
- The colour of processed indicators may fade out under influence of excessive daylight.

Warranty:

- Etigam BV warrants to the original purchaser that Etigam's sterilization process indicators are free from manufacturing defects that would adversely affect its performance.
- Etigam BV warrants that the sterilization process indicators meet Etigam's specifications at the time of shipment to the customer.
- The warranty to the primary functionality of the sterilization process indicators is valid for the duration of the shelf life stated on the product label.
- On request Etigam BV provides samples to validate the sterilization process for the intended use by the customer. In every case user should perform its own test to determine whether the sterilization process indicators are safe and of acceptable quality and suitable under the users cycle parameters.
- Should sterilization process indicators prove defective, Etigam BV will exchange those found defective for others or timely refund the purchase price as Etigam bv determines.
- This warranty shall not apply if the sterilization process indicators are used contrary to the 'Instructions for use' on the packaging or the 'General information sheet' which can be downloaded on the website: www.etigam.nl.
- Under no circumstances will Etigam BV be liable for any incidental or consequential damages.
- Etigam BV does not offer any other warranty and does not warrant the performance, safety or other issues of products in combination with other materials.
- This warranty is made in lieu of all other warranties, expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. In all cases Dutch law is applicable.

ETIGAM BV
The Netherlands

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