Etigam
STERILIZATION INDICATORS

General Information Sheet Ethylene Oxide Sterilization Process Indicators

Description

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

Etigam BV EO sterilization process indicators are EO sensitive labels which undergo a significant colour change from violet to green when exposed to ethylene oxide. The shade of green depends on the sterilization conditions used, e.g.: EO concentration, gas-mixture, sterilization time, preconditioning, temperature and relative humidity.

Etigam BV EO 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 from 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 ethylene oxide at an external facility under the following conditions:

Cycle	EO concentration (mg /l)	Gas mixture (% EO)	Temperature (°C)	Relative humidity (%)	Exposure time (hrs)
1	450	100	55	50-80	2
2	650	100	45	50-80	3

Recommended storage conditions (before and after exposure)
The sterilization process indicators should be stored in dark and dry conditions, between 10 and 30° C (50 and 86° F).

Shelf life

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

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Instructions for use

- Sterilization process indicators may not perform properly unless stored under proper conditions as stated on the package labels.
- Sterilization process indicators must be protected from exposure to excessive daylight and heat, chemicals, chemical vapours and liquids.
- The colour of processed indicators may fade out under influence of excessive daylight.
- Wound rolls exposed to storage conditions above 70% RH will become tighter, avoid this situation to prevent damage to the product.
- Contact between medical devices and sterilization process indicators must be prevented.
- Contact between the sterilization process indicators and material containing plasticizers may cause effect on the performance of the sterilization process indicators.
- Contact between the sterilization process indicators and packaging materials may interfere with proper colour development.
- 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 presence of carbon dioxide may impair the colour change of EO sterilization process indicators. Where the formulation is such that this may occur, process validation is always recommended.

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.
- Etigam BV provides samples on request to validate the sterilization process for the intended use by the customer. Users should always perform their own test to determine whether the sterilization process indicators are safe, of acceptable quality and suitable under the users cycle parameters.
- If sterilization process indicators are proven to be defective, Etigam BV will exchange defective indicators for new ones or a refund, which is determined by Etigam BV.
- This warranty does not apply when the use of the sterilization process indicators is in conflict with the 'Instructions for use' on the packaging or the 'General Information Sheet' which can be downloaded from the website: www.etigam.nl
- Etigam BV is under no circumstances 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 our 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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