DESCRIPTION

EtO sterilization process indicators are EtO sensitive labels which undergo a visual color change when exposed to ethylene oxide. The shade of green depends on the sterilization-conditions used, e.g.: ETO concentration, gas-mixture, sterilization time, preconditioning, temperature, relative humidity and steam-injection.

EtO sterilization process indicators should not be used as a substitute for proper dosimetry, but rather to distinguish EtO exposed products from unexposed.

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

Indicators manufacturer holds the ISO 9001 quality management system certificate for the scope "production, testing, storage, sales and dispatch of chemical indicators coated and/or printed on paper, and supply of biological indicators".

QUALITY CONTROL

Samples of each batch have been tested, before released for sale under the following conditions :

Cycle	1	2
Gas mixture (%ETO)	100	100
ETO concentration (mg/l)	480	625
Temperature (°C)	40	40
R.H. (%)	50-80	50-80
Time (hrs)	2	3

STORAGE CONDITIONS

The indicators must be stored in dark and dry conditions at room temperature (between 10 and 30°C or 50 and 86°F).

SHELF LIFE

The shelf life of unexposed indicators is 24 months after date of production, when stored under proper conditions.

INSTRUCTION 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.
- The presence of carbon dioxide may impair the colour change of ETO sterilization process indicators. Where the formulation is such that this may occur process validation is always recommended. Contact between medical devices and sterilization process indicators must be prevented.
- 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.

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WARRANTY

- SÜDPACK MEDICA SAS warrants to the original purchaser that sterilization process indicators are free from manufacturing defects that would adversely affect its performance.
- SÜDPACK MEDICA SAS warrants that the sterilization process indicators meet 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 SÜDPACK MEDICA SAS 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, SÜDPACK MEDICA SAS will exchange those found defective for others or timely refund the purchase price as SÜDPACK MEDICA SAS 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 SÜDPACK MEDICA SAS be liable for any incidental or consequential damages.
- SÜDPACK MEDICA SAS does not offer any other warranty and does not warrant the performance, safety or other issues of products in combination with other materials.

Article number : 7600004, 7600005, 7600006

Article	Description	E.O. UNEXPOSED	E.O. EXPOSED
7600004	'plain' indicator, circular, Ø 12,7 mm		
7600005	indicator, circular, Ø 12,7 mm, with text: 'green is ETO exposed'.		
7600006	indicator 26 x 12 mm. Can be applied easily and fast with a Meto gun as used in supermarkets		

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