Description :

Gamma / E-Beam sterilization process indicators are radiation sensitive labels which undergo a visual colour change from yellow to red when exposed to Gamma - or Electron beam radiation. The colour change of the indicators is dose dependent.

Gamma / E-Beam sterilization process indicators should not be used as a substitute for proper dosimetry, but rather to distinguish Gamma / E-Beam exposed products from unexposed products.

Indicators manufacturer Gamma / E-Beam sterilization 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:

Before and during the production process the materials and indicators undergo several scheduled internal checks.
Samples of each batch have been gamma irradiated at an external facility, before being released for sale with an average dose of:

- 10 kGy (1.0 Mrad)
- 15 kGy (1.5 Mrad)
- 25 kGy (2.5 Mrad)

Storage conditions:

Dark and cool (between 2° and 22°C or 35° and 72°F).

Shelf life:

The shelf life of unexposed indicators is 24 months after date of production.

Precautions:

The indicators must be protected from exposure to UV light, sunlight, excessive heat, chemicals or chemical vapours. Covering the indicators with packaging materials containing plasticizers may cause colour reversion.

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.

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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 :

- 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 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 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 : 7600014, 7600015,7600016, 7600018, 7600019, 7600020, 7600022, 7600023, 7600024, 7601581.
Other article is are dedicated for special design for specific customer request.

This technical data sheet doesn't release from the responsibility to check the suitability of packaging material for the proposed application. This information may be subject to change without notice.

Article	Description	No irradiated	Irradiated
7600015	'plain' indicator, circular, Ø 12,7 mm		
7600016	Indicator 26 x 12 mm. Can be applied easily and fast with a Meto gun (handapplicator as used in supermarkets)		
7600018	14 x 14 mm., with printed circle, text: 'red is exposed'		
7600019	14 x 14 mm., with text; 'red is ß exposed'		
7600022	Indicator 26 x 12 mm. Can be applied easily and fast with a Meto gun (handapplicator as used in supermarkets)		
7600023	Indicator 117x48mm with printed band 7x48 mm		

Other article is dedicated for special design for specific customer request. The design and drawing are validated by customer.

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