

# Sterilization Indicators

Biological indicators  
for monitoring sterilization  
processes



 **Etigam**  
STERILIZATION  
INDICATORS

*Visual evidence at your fingertips*

# Introduction to our biological indicators for monitoring sterilization processes

## **BIOLOGICAL INDICATORS (BI'S) ARE GENERALLY ACCEPTED AS THE MOST SUITABLE DEVICE TO USE FOR MONITORING STERILIZATION PROCESSES ON THEIR EFFECTIVENESS AND THE LETHALITY OF THE USED STERILIZER.**

The BI's contain a specific micro organism that is proven to be highly and stable resistant to the used sterilization process. The BI's are used to assist in sterilization processes that render a product sterile in its final package or container, as well as for the sterilization of equipment, materials and packaging components used in aseptic processing. Etigam BI's are conventional spore growth readout indicators specifically designed for reliable monitoring of sterilization processes without the use of enzyme based technology or specific and specialized incubators or monitoring devices. Etigam biological indicators comply with the performance requirements of ANSI/AAMI/ISO 11138-1 and the USP requirements.



## Etigam product range

### Spore suspensions

NSU spore suspensions are used to inoculate products undergoing sterilization. They are available for use in Steam, Ethylene Oxide, Dry heat and Gamma/E-beam sterilization processes.

Spore suspensions are provided with population and resistance values to the sterilization process.

Each vial contains 10 ml of spore suspension in 20% ethanol or water.



Micro-organism	Sterilization Process	Incubation Time	Incubation Temperature	Etigam Productcode
Geobacillus stearothermophilus	Steam	7 days	60 °C	NSU-S5/6
Bacillus atrophaeus	EO gas & Dry heat	7 days	37 °C	NSU-E6
Bacillus pumilus	Gamma / E-beam	7 days	35 °C	NSU-R6

Other populations are available on request.

## Self-contained indicators

Etigam NSC self-contained biological indicators are available for monitoring the efficacy of Steam, H2O2/ Plasma and Ethylene Oxide sterilization processes. They contain bacterial spores on a paper carrier (or tyvek disc for H2O2/plasma) plus a sealed glass ampoule within a vented plastic vial.

The glass ampoule contains a proprietary formulation of soybean casein digest culture media with a pH indicator. The pH indicator remains purple when there is no spore growth and turns yellow when there is spore growth. This allows quick visual detection of sterilization failure (yellow colour).



Micro-organism	Sterilization Process	Incubation Time	Incubation Temperature	Etigam Productcode
Geobacillus stearothermophilus 10 <sup>5</sup>	Steam	24 hours	60 °C	NSC-S5
Geobacillus stearothermophilus 10 <sup>6</sup>	Steam	24 hours	60 °C	NSC-S6
Geobacillus stearothermophilus 10 <sup>5</sup>	Steam	10 hours	60 °C	NRI-S5
Geobacillus stearothermophilus 10 <sup>6</sup>	Steam	10 hours	60 °C	NRI-S6
Geobacillus stearothermophilus 10 <sup>6</sup>	H2O2 / Plasma	24 hours	60 °C	NSC-H6
Bacillus atrophaeus 10 <sup>6</sup>	EO gas	48 hours	37 °C	NSC-E6

## Spore strips

NSS spore strips are traditional biological indicators used to monitor Steam, Ethylene Oxide, Dry heat and Gamma / E-Beam sterilization processes.

They contain bacterial spores on a paper carrier strip within a peel open glassine envelope.



Micro-organism	Sterilization Process	Incubation Time	Incubation Temperature	Etigam Productcode
Geobacillus stearothermophilus 10 <sup>5</sup> or 10 <sup>6</sup>	Steam	7 days	60 °C	NSS-S5/6
Bacillus atrophaeus 10 <sup>6</sup>	EO gas & Dry heat	7 days	37 °C	NSS-E6
Bacillus pumilus 10 <sup>6</sup>	Gamma / E-beam	7 days	35 °C	NSS-R6
Geobacillus stearothermophilus 10 <sup>5</sup> / Bacillus atrophaeus 10 <sup>6</sup>	Steam, EO gas & Dry heat	7 days	60 °C	NSS-C1

Other populations and dimensions are available on request.

## Ampoules for sterilization of liquids

Etigam biological indicator spore ampoules are used to monitor industrial steam processes for sterilization of liquids. They contain bacterial spores together with a culture medium in a closed glass ampoule, and respond with a colour change on sterilization failure.



Micro-organism	Sterilization Process	Incubation Time	Incubation Temperature	Etigam Productcode
Geobacillus stearothermophilus 10 <sup>6</sup> - 0.4 ml	Steam	24 hours	60 °C	NAS-S6
Geobacillus stearothermophilus 10 <sup>6</sup> - 1 ml	Steam	24 hours	60 °C	NAL-S6
Negative Control (no spores)	Steam	24 hours	60 °C	NAL-NC

## Special products available on request

different species :

- b. clostridium
- e-coli
- bac. cereus

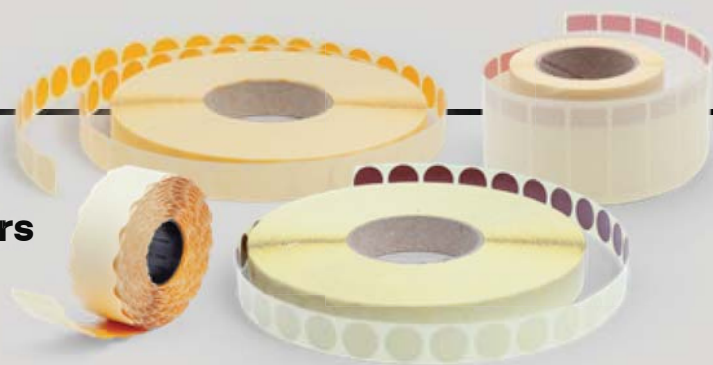
different carriers :

- tyvek
- stainless steel discs
- paper discs (6 mm)
- ministrips (2 x 10 mm)
- cotton threads

## Also available

### Self adhesive sterilization process indicators

that change colour during the sterilization process



The print methods which are used to produce this folder differ from the methods used in our indicator products.

 **Etigam**  
STERILIZATION  
INDICATORS



**Etigam bv**  
Prinsenweide 30  
7317 BB Apeldoorn  
The Netherlands

**Phone** +31 55 5211721  
**E-mail** info@etigam.nl  
**Internet** www.etigam.nl