# Sterilization Indicators

Self-adhesive process indicators that change color during sterilization

SteriMark Inc. 8

STERILIZATION INDICATORS Visual evidence at your fingertips

DARK BROWN IS EXPOSED (121 °C & 134 °C) DARK BROWN IS EXPOSED (121 °C & 134 °C)

ETIGAM STEAM PROCESS INDICATOR

## Introduction to our sterilization indicators

AN ESSENTIAL PART OF ANY STERILITY-ASSURANCE PROGRAM IS THE CHEMICAL STERILIZATION PROCESS INDICATOR. ETIGAM INDICATORS CAN BE USED IN GAMMA, E-BEAM, X-RAY, EO GAS AND STEAM PROCESSES.

Etigam type 1 sterilization indicators are developed to provide visual evidence that products have been processed. They respond with a significant color change on the defined minimum sterilization performance requirements. Sterilization indicators are used to allow differentiation between processed and unprocessed items, and/or indicate gross failure of a sterilization process. Etigam indicators are manufactured following the guidelines of ISO 11140-1:2014 "Sterilization of health care products – chemical indicators – part 1: General requirements".



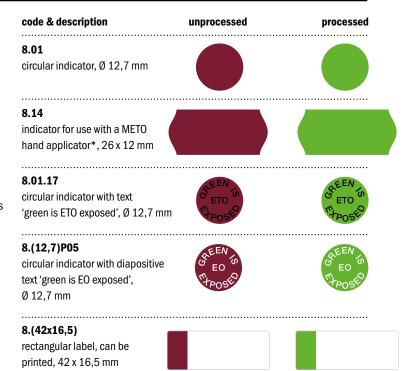
#### EO

## Sterilization process indicators

Color change violet - green



Etigam self-adhesive EO gas indicators provide visual evidence that items have been processed. They respond to physical conditions during the process with a significant color change from violet to green. The shade of green may vary depending on the process parameters used (time, temperature, gas concentration, gas mixture etc.). Standard indicators can be supplied from inventory. Customized labels are available upon request.



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IRRAD

## Sterilization process indicators

Dose range >10 kGy (>1 Mrad) code & description non-irradiated irradiated Color change yellow - red 2.01 circular indicator, Ø 12,7 mm Etigam self-adhesive irradiation indicators provide visual evidence FD 2.01 Y Exp γ that items have been exposed. They circular indicator with text 'red is POS respond to gamma, e-beam and γ exposed', Ø 12,7 mm x-ray radiation with a significant color ..... 2.12.04 change from yellow to red. Standard indicators can be supplied from square indicator with printed circle with text 'red is y exposed', inventory. Customized labels are 14 x 14 mm available upon request. 2.12.06 REDIO Applications include: square indicator with text 'red is · sterilization of medical and  $\beta$  exposed', 14 x 14 mm pharmaceutical products ..... · cross linking of polymers 2.14 · preservation of foodstuffs indicator for use with a METO · decontamination of herbs hand applicator\*, 26 x 12 mm and spices ..... ..... 2.(52x17) rectangular label, can be printed, 52 x 17 mm Dose range > 6 kGy (0,6 - 1 Mrad) 3.3.01 Color change green - violet circular indicator, Ø 12,7 mm Sterilization process indicators **STEAM** 

121°C/1 bar or 134°C/2 bar Color change pink – dark brown



Etigam self-adhesive steam indicators provide visual evidence that items have been exposed. They respond to physical conditions inside an autoclave with a significant color change from pink to dark brown. Standard indicators can be supplied from inventory. Customized labels are available upon request.

code & description	unprocessed	processed
<b>4.01</b> circular indicator, Ø 12,7 mm		
4.(38x14)	DARK BROWN IS EXPOSED (121 °C & 134 °C)	DARK BROWN IS EXPOSED (121 °C & 134
rectangular label, with text, 38 x 14 mm	ETIGAM STEAM PROCESS INDICATOR	ETIGAM STEAM PROCESS INDICATO
4.(42x16)		
rectangular label, can be printed, 42 x 16 mm		

images 8.(42x16), 2.(52x17), 4.(38x14) and 4.(42x16) not at actual size \*Can be applied easily and fast with a METO hand applicator



Customized product labels are available in various dimensions. Etigam can supply these upon request. They are already provided with an indicator dot or strip, reducing the time and costs of additional handling. The product labels can also be pre-printed with company details.



#### ADVANTAGES:

- · saving on labor
- · consistent positioning of the indicator
- · labels available for thermal or thermo transfer
- · high visibility
- batch identification and visual sterilization evidence on 1 label



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



## Other special products

A wide range of other products is available in addition to the products mentioned in this brochure.

#### 1.1.01

irradiation indicator, color change yellow - violet

non-irradiated irradiated





#### 5.3.01.07

irradiation indicator, color change green - violet, striped design

non-irradiated





#### PE labels and cores

on request available on PET backing and PE cores .....

#### VH2O2 indicator tape

for use in hydrogen peroxide (plasma) cycles

#### **METO hand applicator**

for fast and easy application, with or without printhead



## Also available

### **Biological Indicators**

SteriMark Inc P.O. Box 352796 Toledo, OH 43635-2796 United States of America

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