

# TYPE 4 STEAM STERILIZATION INDICATOR



## Product description

Type 4 steam sterilization indicator was designed to control the critical parameters of the process: temperature, time and steam. The yellow indicator ink reacts changing slowly from yellow to black at the end of the process, showing that the parameters were achieved. The strip is printed with two identical indicators on both ends, placed on a support made a of a special paper of 180 g/m.

## Presentation

Boxes contain 250 double strips of 160 x 15 mm. Package includes instructions for use, description and expiration date. Indicator strips show lot number.

## Classification

Type 4 Multiparameter Indicator for steam sterilization process complies with ISO 11140-1:2014 standards.

## Shelf-life

36 months from the date of manufacture

## Stability

Steam: Saturated, maximum steam quality 0.95  
Temperature: 121 °C  
Time: 15 minutes

Steam: Saturated, maximum steam quality 0.95  
Temperature: 134 °C  
Time: 3.5 minutes

## Quality control

Quality system according to ISO 9001: 2015, ISO 13485:2016 and GMP (Good Manufacturing Practices).

## Authorization and habilitation

ANMAT: PM 1454-44

## Technical characteristics

Lead free indicator, sensitive to saturated steam, exposure time and temperature. The indicator reacts through the combination of exposure time, temperature and saturated steam with the quality necessary to produce microcondensation. Indicator reacts differently if steam is dry and doesn't allow condensation on the strip. If steam is moist and the strip gets wet, results may not be trustworthy. Steam quality should be between 0.90 and 0.95. Lower values of steam quality can produce undesirable wet material and strip. Steam quality values above 0.95 may cause overheating and prevent microcondensation, making sterilization ineffective.

## Utilization

Internal and external indicator for steam sterilization processes. Strips must be placed inside or outside items to sterilize. Once the sterilization cycle is finished, the strip changes its color according to the stated values. Usual color change is from yellow to black. Dark brown as a final color can be considered correct. Endpoint color stays indefinitely.





## Cautions and warnings

Strips should be kept in the original package until use. Storage temperature should be between 5 and 50 °C. Moisture should be avoided to prevent inactivation of reactants upon exposure. If the indicator accidentally gets wet must be discarded and cannot be used. Avoid contact with, or storage near volatile chemicals, cleaning agents and adhesives to prevent alterations in the indicator.

## Steam sterilization

Steam sterilization is the most widely used sterilization method. Steam autoclaves are usually prepared to sterilize at two temperatures, 134 °C and 121 °C, although intermediate values are also used. Steam sterilization indicators should be prepared to detect time and temperature of the process, as well as the steam quality to guarantee microcondensation, and consequently, the efficiency of the process.

## Results guide

Unprocessed	Processed
  Indicador de esterilización Sterilization indicator VAPOR / STEAM VIRA A MARRÓN / NEGRO TURNS TO BROWN / BLACK TIPO 4 / TYPE 4 ISO 11140-1 (2014) LOT J 750 / K 500	  Indicador de esterilización Sterilization indicator VAPOR / STEAM VIRA A MARRÓN / NEGRO TURNS TO BROWN / BLACK TIPO 4 / TYPE 4 ISO 11140-1 (2014) LOT J 750 / K 500