

# TYPE 4 DRY HEAT STERILIZATION INDICATOR



## Product description

Type 4 dry heat indicator was designed to control the critical parameters of the process: time and temperature. The indicator ink reacts changing slowly from violet to brown/black at the end of the process. Dark brown color indicates that minimum parameters of time and temperature were achieved. More exposed zones of the indicator may reach a black color. The strip is printed with two identical indicators on both ends, placed on a support made of a special paper of 180 g/m<sup>2</sup>. It contains highly adhesive acrylic resins that assure firm fixation of the indicator on the paper under heat exposure at high temperature.

## 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 Indicator for dry heat sterilization process complies with ISO 11140-1:2014 standards.

## Shelf-life

36 months from the date of manufacture

## Stated values

Temperature: 160 °C | Time: 120 min

Temperature: 170 °C | Time: 60 min

Temperature: 180 °C | Time: 30 min

## Quality control

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

## Stability

Stability has been verified from manufacture to expiration date, 36 months after date of manufacture.

## Authorization and habilitation

ANMAT: PM 1454-44

## Technical characteristics

Indicator contains neither sulfur nor lead. Due to the absence of sulfur, the equipment does not get dirty and there is no odor.

## Directions for use

Internal and external indicator for dry heat 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 violet to black. 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.

## Dry Heat Sterilization

Dry heat is the most direct sterilization method and is used when steam sterilization is not possible in materials resistant to high temperatures. It is a slow method as heat must be transferred through air, which is a low efficiency process. In spite of this, it is the only possible method when sterilizing materials that cannot get wet such as talc or vaseline. Dry heat sterilization uses higher temperatures than steam. The most used cycle is 170 °C / 2 hours. The equipment used is very simple and cheaper than an autoclave, generally a hot air oven with temperature regulation.

## Results Guide

