Technical Data Sheet

Reference: 4500014007

TYPE 5 STEAM STERILIZATION INDICATOR

Product description

Type 5 steam sterilization indicator was designed to control the critical parameters of the process: temperature, time and steam.

The indicator ink reacts changing slowly from red to yellow at the end of the sterilization process, showing that the parameters were achieved.

The strip is printed on a neutral laminated support of 150 g/m² and has a red indicator and a yellow pattern that shows the expected final color.

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

Minimum stated values

Temperature: 121 °C
Time: 12 min

Temperature: 134 °C
Time: 4 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

Lead free indicator sensitive to steam through a color change. The reactant is specific to steam.

Laminate specially designed for steam that stays firmly fixed on the paper during the sterilization cycle and guarantees the stability of the reactant until its use.

The reactant changes from red to yellow, detecting the energy accumulation necessary to achieve sterilization.

Best results are obtained when used as an internal reactant, placed in closed packages.

The indicator endpoint follows the sterilization curve of biological indicators, without taking into account the initial iner a of the autoclave or heating conditions. In autoclaves specially designed to calibrate chemical and biological indicators, color change occurs at 121 °C – 12 minutes with a 63.5 % tolerance in time.

Permanence of the indicator for more minutes than indicated to sterilize does not alter its final color.

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 from red to yellow. Endpoint color stays indefinitely if stored in adequate conditions.

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

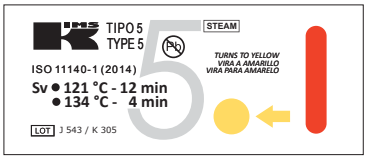
Steam sterilization is the most widely used sterilization method. Steam autoclaves are usually prepared to sterilize at two temperatures, 134 °C and 121 °C, although intermediate values are also used. Steam sterilization indicators should be prepared to detect time and temperature of the process, as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

Types of indicators

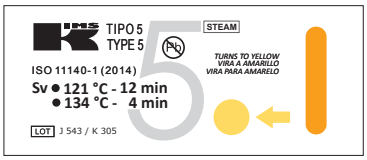
ISO 11140-1:2014 specifies 6 types of sterilizton indicators which basically differ in their precision. Among them, type 5 indicators, also called integrators, must follow the death rate curve of biological indicators.

The 2005 version of the document used the term “class” instead of “type” to describe the use of indicators.

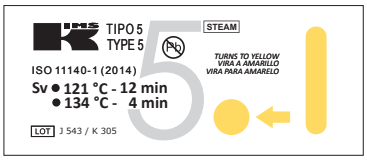
Results guide



Unprocessed



Insufficient process



Correct process