

TYPE 6 STEAM STERILIZATION INDICATOR



Product description

Type 6 steam sterilization indicator was designed to control the critical parameters of the process: temperature, time and steam.

The indicator ink reacts changing slowly from violet to green 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 violet indicator and a green pattern that shows the expected final color.

Presentation

Boxes contain 200 strips of 75 x 21 mm. Package includes instructions for use, description and expiration date. Indicator strips show lot number.

Classification

Type 6 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: 134 °C
Time: 3.5 min

Stability

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

Authorization and habilitation

ANMAT: PM 1454-44

Quality control

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

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 even under extreme temperature conditions and guarantees the stability of the reactant until its use.

The reactant changes from violet to green, detecting the energy accumulation necessary to achieve sterilization.

The reactant is prepared to support extreme conditions such as contact with metals and autoclave parts. Best results are obtained when used as an internal reactant, placed in closed packages.

The indicator reaches the endpoint when the stated values of time are completed at the indicated temperatures. The initial inertia of the autoclave may cause the color to change before or after the usual time. The reactant is designed for high vacuum autoclaves with an intermediate inertia of approximately 6 minutes considering 3 vacuum cycles, which is common in small autoclaves. Sterilization begins after the initial 6 minutes.

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

Directions for use

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 violet to green. 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.

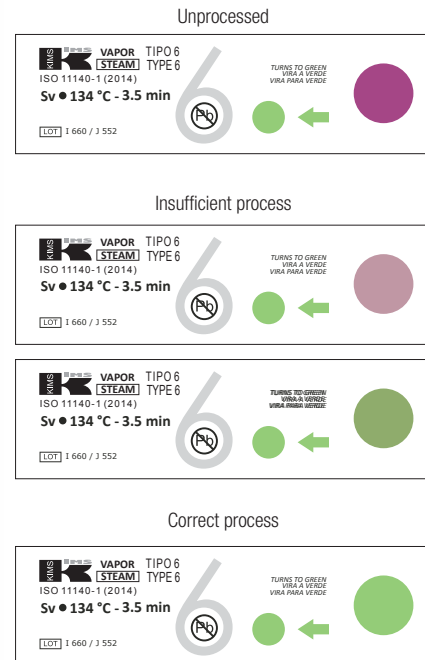
Steam sterilization

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 sterilization indicators which basically differ in their precision. Among them, type 6 indicators, also called emulators, measure time, temperature and vapor presence, and try to emulate the cycle they quantify. Emulators are specific for each cycle, all of them will eventually reach the same final color with longer cycles than the indicated in the stated values. The 2005 version of the document used the term "class" instead of "type" to describe the use of indicators.

Results guide



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Presentation

Boxes contain 200 strips of 75 x 21 mm. Package includes instructions for use, description and expiration date. Indicator strips show lot number.

Classification

Type 6 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

Stability

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

Authorization and habilitation

ANMAT: PM 1454-44

Quality control

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

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 even under extreme temperature conditions and guarantees the stability of the reactant until its use.

The reactant changes from violet to green, detecting the energy accumulation necessary to achieve sterilization.

The reactant is prepared to support extreme conditions such as contact with metals and autoclave parts. Best results are obtained when used as an internal reactant, placed in closed packages.

The indicator reaches the endpoint when the stated values of time are completed at the indicated temperatures. The initial inertia of the autoclave may cause the color to change before or after the usual time. The reactant is designed for high vacuum autoclaves with an intermediate inertia of approximately 6 minutes considering 3 vacuum cycles, which is common in small autoclaves. Sterilization begins after the initial 6 minutes.

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

Directions for use

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 violet to green. 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.

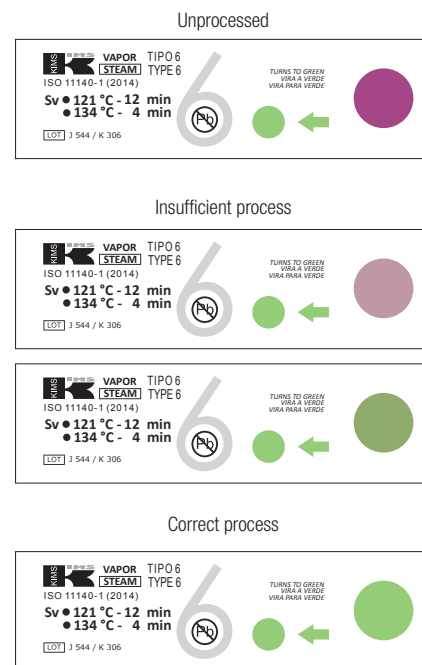
Steam Sterilization

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 sterilization indicators which basically differ in their precision. Among them, type 6 indicators, also called emulators, measure time, temperature and vapor presence, and try to emulate the cycle they quantify. Emulators are specific for each cycle, all of them will eventually reach the same final color with longer cycles than the indicated in the stated values. The 2005 version of the document used the term "class" instead of "type" to describe the use of indicators.

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Presentation

Boxes contain 200 strips of 75 x 21 mm. Package includes instructions for use, description and expiration date. Indicator strips show lot number.

Classification

Type 6 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: 15 min

Temperature: 134 °C
Time: 5.3 min

Stability

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

Authorization and habilitation

ANMAT: PM 1454-44

Quality control

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

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 even under extreme temperature conditions and guarantees the stability of the reactant until its use.

The reactant changes from violet to green, detecting the energy accumulation necessary to achieve sterilization.

The reactant is prepared to support extreme conditions such as contact with metals and autoclave parts. Best results are obtained when used as an internal reactant, placed in closed packages.

The indicator reaches the endpoint when the stated values of time are completed at the indicated temperatures. The initial inert a of the autoclave may cause the color to change before or after the usual time. The reactant is designed for high vacuum autoclaves with an intermediate inert a of approximately 6 minutes considering 3 vacuum cycles, which is common in small autoclaves. Sterilization begins after the initial 6 minutes.

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

Directions for use

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 violet to green. Endpoint color stays indefinitely if stored in adequate conditions.

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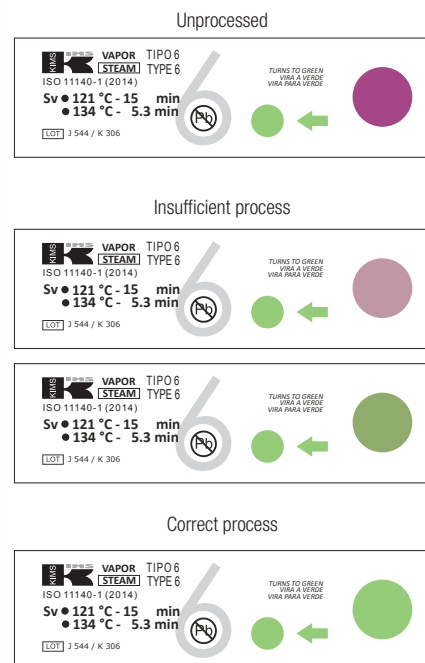
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Classification

Type 6 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: 20 min

Temperature: 134 °C
Time: 7 min

Stability

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

Authorization and habilitation

ANMAT: PM 1454-44

Quality control

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

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