Technical Data Sheet

Reference: 4500002013

TYPE 4 FORMALDEHYDE STERILIZATION INDICATOR

Product description

Type 4 formaldehyde sterilization indicator was designed to control the critical parameters of the process: presence of formaldehyde, saturated steam and exposure time. The indicator ink reacts to the sterilization parameters, gradually changing from initial green to yellow at the end of the process, showing that the parameters were achieved. The strip is laminated and printed on a neutral support of 150 g/m², has a green indicator and a yellow pattern that matches the expected final color as best as possible.

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 4 indicator for formaldehyde sterilization process complies with ISO 11140-1:2014 standards.

Shelf-life

36 months from the date of manufacture

Stated values

Concentration: 2 g/L
Saturated steam: 123 mb
Temperature: 50 °C
Time: 120 min

Concentration: 2 g/L
Saturated steam: 200 mb
Temperature: 60 °C
Time: 60 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 the presence of formaldehyde at a temperature above 50 °C. Reactant combines with formaldehyde producing an irreversible color change. The indicator is stable at room temperature even if exposed to formaldehyde and does not react with saturated steam in absence of formaldehyde.

Directions for use

Internal and external indicator for formaldehyde sterilization processes. Strips must be placed inside or outside items to sterilize. Once the sterilization cycle is finished, the color of the strip changes according to the stated values, from green to yellow, similar to the pattern. 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. High relative humidity levels 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 and cleaning agents such as bleach and ammonia. Avoid specially contact with adhesives to prevent alterations in the indicator due to the presence of aggressive agents.

Formaldehyde Sterilization

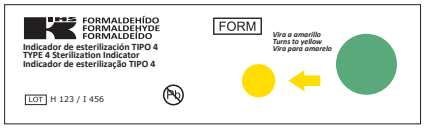
Formaldehyde sterilization is a method that uses the action of formaldehyde in combination with saturated steam at a temperature above 50 °C. This is the reason why “low temperature steam formaldehyde”, LTSF, corresponds to formaldehyde and low temperature steam. Autoclaves of this kind use 2% formaldehyde and pressure values below atmospheric to allow water to vaporize at low temperature. Sterilization indicators must change color only in presence of low proportion of formaldehyde and must not change color in presence of steam without formaldehyde.

Types of indicators

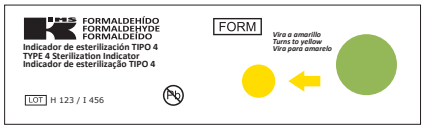
ISO 11140-1:2014 specifies that only type 1 and type 4 formaldehyde sterilization indicators are admitted due to difficulties in testing. The fundamental requirement for these indicators in presence of water steam without formaldehyde is remaining unchanged or changing to a different color than the expected in presence of formaldehyde. Low concentrations of formaldehyde are very common in many places, because of agglomerated woods made with formaldehyde resins. Therefore, it is very important that indicators do not react at room temperature with formaldehyde as this could affect their stability.

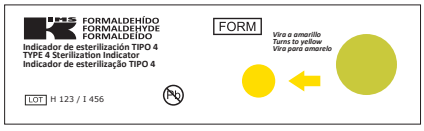
Results guide

Unprocessed



Insufficient process





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