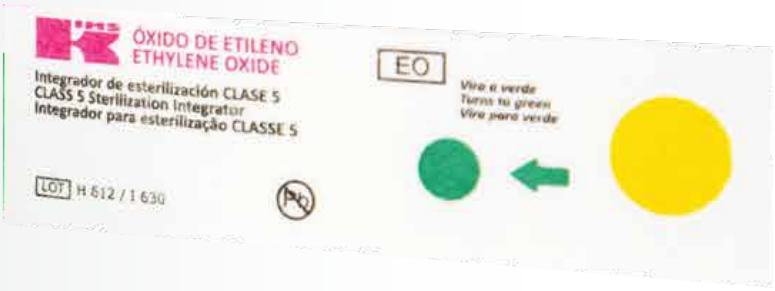
Technical Data Sheet

Reference: 4500004003

TYPE 5 ETHYLENE OXIDE STERILIZATION INDICATOR



Product description

Type 5 ethylene oxide sterilization indicator was designed to control the critical parameters of the process: ethylene oxide concentration, temperature, time and relative humidity. The indicator ink reacts to the sterilizatuon parameters, gradually changing from yellow to green at the end of the process, showing that the parameters were achieved. The strip is printed on a neutral laminated paper of 150 g/m², with a yellow 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 and green pattern.

Classification

Type 5 Indicator for ethylene oxide sterilization process complies with ISO 11140-1:2014 standards.

Shelf-life

36 months from the date of manufacture

Stated values

Concentration: > 450 mg/L
Temperature: 55 °C
Time: 240 min
RH: > 60 %

Concentration: > 450 mg/L
Temperature: 37 °C
Time: 360 min
RH: > 60 %

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 ethylene oxide during an established time and temperature. The indicator reacts indirectly with ethylene oxide, activating the change of a specific dye's color. For this reaction to occur, a minimum relative humidity is necessary. The indicator does not react or the reaction is not efficient if humidity is below 60%. Low relative humidity values may allow a correct color change of the indicator and revert after a few hours.

Directions for use

Lead free indicator sensitive to the presence of ethylene oxide during an established time and temperature. The indicator reacts indirectly with ethylene oxide, activating the change of a specific dye's color. For this reaction to occur, a minimum relative humidity is necessary. The indicator does not react or the reaction is not efficient if humidity is below 60%. Low relative humidity values may allow a correct color change of the indicator and revert after a few hours.

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.

Ethylene oxide sterilization

Sterilization with ethylene oxide is the oldest low temperature sterilization method. Ethylene oxide is an explosive and poisonous gas, which is the reason why autoclaves have rigorous safety measures. Sterilization processes are carried out between 35 and 55 °C, at different times and concentrations. Indicators are usually calibrated for the most commonly used sterilization cycles, as it is unlikely to cover all possible processes. The most critical sterilization factor is relative humidity, which should always be above 50%. Ethylene oxide has an extraordinary penetration power. Therefore, is a very used method for large scale industrial sterilization processes.

Types of indicators

ISO 11140-1:2014 specifies 6 types of sterilization 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

Insufficient process

Correct process