ΕN

IT27-3.5SAD

Unique Point Emulator Indicator

For Steam sterilization processes. With self-adhesive support.



Usage

Control of Steam sterilization processes.

Emulation conditions: 3.5 minutes, 134 °C (FLASH cycles).

Applicable Regulation

ISO 11140-1:2014

Classification

Class 1, according to risk.

Authorization

Designed under Quality Management Systems standards ISO 13485:2003/NS-EN ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-4.

Characteristics

Type 6 Emulator Indicator.

Strips printed with indicator ink. Version of the emulator indicator in a self-adhesive support, which allows their easy record.

Size: 72 mm x 23 mm.

Initial color: purple

Final color: green

100 % Toxic Heavy Metals free













The product ensures an adequate control of the efficacy of sterilization processes (temperature, time, quality of steam).

Environmental conditions during manufacture

15-30 °C (room temperature), RH 30-80 %.

Storage conditions

T = 10-30 °C, RH 30-80 %, keep out of direct light.

Transportation conditions

Storage conditions should be strictly followed. Transport in closed and reinforced boxes in order to avoid damages. Transportation of this product does not represent a risk for health.

Shelf-life

5 years



Integron

Packing

100 units per box.

Packing information: product code and description, process for intended use, operating instructions, product presentation, classification according to regulation, batch number, manufacturer information and expiration date.

Labelling

Information only on product's package.

Possible target markets

Healthcare, Food, Pharmaceutical and Medical Industries.

Other important information (optional)

Read product's directions for use thoroughly before use.

Note: When necessary, limits for each product's parameters should be specified.

Description of identified and/or predictable risks which could represent a risk for the product

Do not store the product near sterilizing agents.

Do not expose this product to EO, Dry Heat or any sterilization processes other than Steam.

Do not reuse the sterilizer until the indicator has changed into the color indicated in the product.

