

IT28

Emulator Indicator

For Steam sterilization processes.



Usage

Control of Steam sterilization processes.

Emulation conditions: 3.5 minutes, 134 °C // 15 minutes, 121 °C.

Applicable Regulation

ISO 11140-1:2014

Classification

Class 1, according to risk.

Authorization

Designed under Quality Management Systems standards ISO 9001:2008 and ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-4.

Characteristics

Type 6 Emulator Indicator.

One-side-laminated cards printed with indicator ink.

Size: 60 mm x 25 mm.

Initial color: **blue**

Final color: **black**

100 % Toxic Heavy Metals free



Note: The non-laminated side can be written.

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

Packing

250 units per aluminium foil bag.

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.

Weight per bag: 102,8 g.

Labelling

Information only on product's box.

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.