

INDICATOR TAPES FOR STEAM STERILIZATION

Manufacturer :

SOGEVA s.r.l.
VIA PIETRO NENNI SNC
23801 CALOLZIOCORTE (LECCO) ITALY

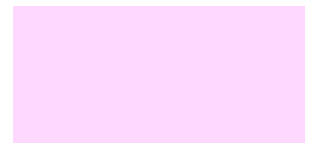
Product's description:

Indicators are made from self-sticking tapes in semicrepe paper of pure cellulose on which there is on one side the adhesive in natural rubber and on the other side the chemical indicators, which recognize the happened process of sterilization for steam sterilization in autoclaves, in compliance to requirement of norm UNI EN 867-1 and 2.

Indicators tapes for steam sterilization have been purposely study to assure the twofold function of closing of the packages to sterilize and to assure the evidence of the happened process of sterilization.

Indicators tapes for steam sterilization belong to "Class A", that is "...destined to the use with single product confection destined to sterilization in order to demonstrate that the confection has been subordinate to the process."

Product's picture:



Technical data:

- Variation of color: from white to brown;
- Range of temperature of application: between 121°C and 134°C;
- Total thickness: 0,150 millimeter, with tolerance of $\pm 2\%$;
- Adhesive force on the steel: 2,5N/cm with tolerance of $\pm 15\%$;
- Lengthening % before the breach: 9%, with tolerance of $\pm 2\%$;



- Breaking Load (it is the maximum applicable force before the breach): 3daN/cm, with tolerance of $\pm 2\%$;

Conformity to the norm:

Indicators tapes for steam sterilization produced from Sogeva S.r.l. are in conformity to the indications previewed from norm UNI EN 867-2 "not biological systems for the use in autoclaves" and just to:

- 5.1.1: *the exposure to dry heat ($140\pm 2^{\circ}\text{C}$) for 30 ± 1 minutes does not determine toning of the indicator (or to the maximum in a marked different way from the process of steam sterilization);*
- 5.1.2: *the exposure of the indicators tapes to process of sterilization by steam to 121°C ($+3/-0$) for a time between 3 and 10 minutes evidence complete toning;*
- 5.1.3: *the exposure of the indicators tapes to process of sterilization by steam to 134°C ($+3/-0$) for a time between 30 second and 2 minutes evidence complete toning;*

This process of verification has been lead from the Laboratory "Studio Ambiente S.r.l." both on new product and as a result of forced aging of 10 weeks to 70°C .

Instructions for use

- *cut a piece of indicator tape of the dimension requested for one corrected closing of the package and stick it;*
- *insert all inside of the autoclave and proceed with the cycle of steam sterilization;*
- *finished the cycle, extract the material and proceed with the verification of the corrected change of the colour of tape from white to brown.*

It is possible to apply a piece of tape on envelopes, in order to, as described in the previous points, make sure the happened process of sterilization.

Note: chemical toning indicators cannot be alone employed as validation to sterilization process. Sogeva S.r.l. does not answer of eventual damages attributable to not corrected uses of the product.

Shelf life

The product has unlimited period of life if kept far from sunlight; only for precaution – as the product is not sterile – we can fix a limit to 5 years from production date.

LIST OF CODES AND MATERIALS:

CODE	SIZES	PACKING
STEAM12S	mm.12x50 mt.	72 Pcs/Carton/kg.6,0
STEAM19S	mm.19x50 mt	48 Pcs/Carton/kg.6,0
STEAM25S	mm.25x50 mt	36 Pcs/Carton/kg.6,0

SOGEVA s.r.l.
VIA PIETRO NENNI SNC
23801 CALOLZIOCORTE
(LECCO)



**TECHNICAL DATA
SHEET**

Storage conditions: keep at room temperature in a cool and dry place, far from sunlight and fire.

CALOLZIOCORTE (LECCO)
13.04.2022

MR MATTEO SALA
SOGEVA SRL - CEO

A handwritten signature in blue ink, appearing to read 'M. Sala', is written over a faint, semi-transparent stamp. The stamp contains the text 'SOGEVA s.r.l.' and 'L. Amministratore'.