

INDICATOR TAPES FOR STEAM STERILIZATION

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."

Code	Sizes	Packing
STEAM12S	12mm x 50 metri	72 pcs

TECHNICAL SPECIFICATIONS

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 $\pm 2\%$;

Shelf life: 5 years.

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±2°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.

TECHNICAL SCHEDULE Ed. 01 dated 29.05.2006

STORAGE CONDITIONS

Keep product in original confection, far away from the direct sources of heat light and humidity. The product is disposable.



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.

DE Healthcare Products

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