

<b>TECHNICAL DATA SHEET PRODUCT</b> <b>EC. STEAM 98.4</b>	Mod. ST61 EN
	Rev. 2
	May 2021

## MANUFACTURER IDENTIFICATION

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## PRODUCT IMAGE



## PRODUCT DESCRIPTION

Chemical Indicator for steam sterilization in laminated cardboard.  
 Printed with the process indicator for steam cycles, covered by plastic film, temperature reagent, water steam and pressure in a period of time established by the normative.  
 The indicator will give a clear evidence of cycle ex position of saturated steam sterilization changing color from blue to black after:

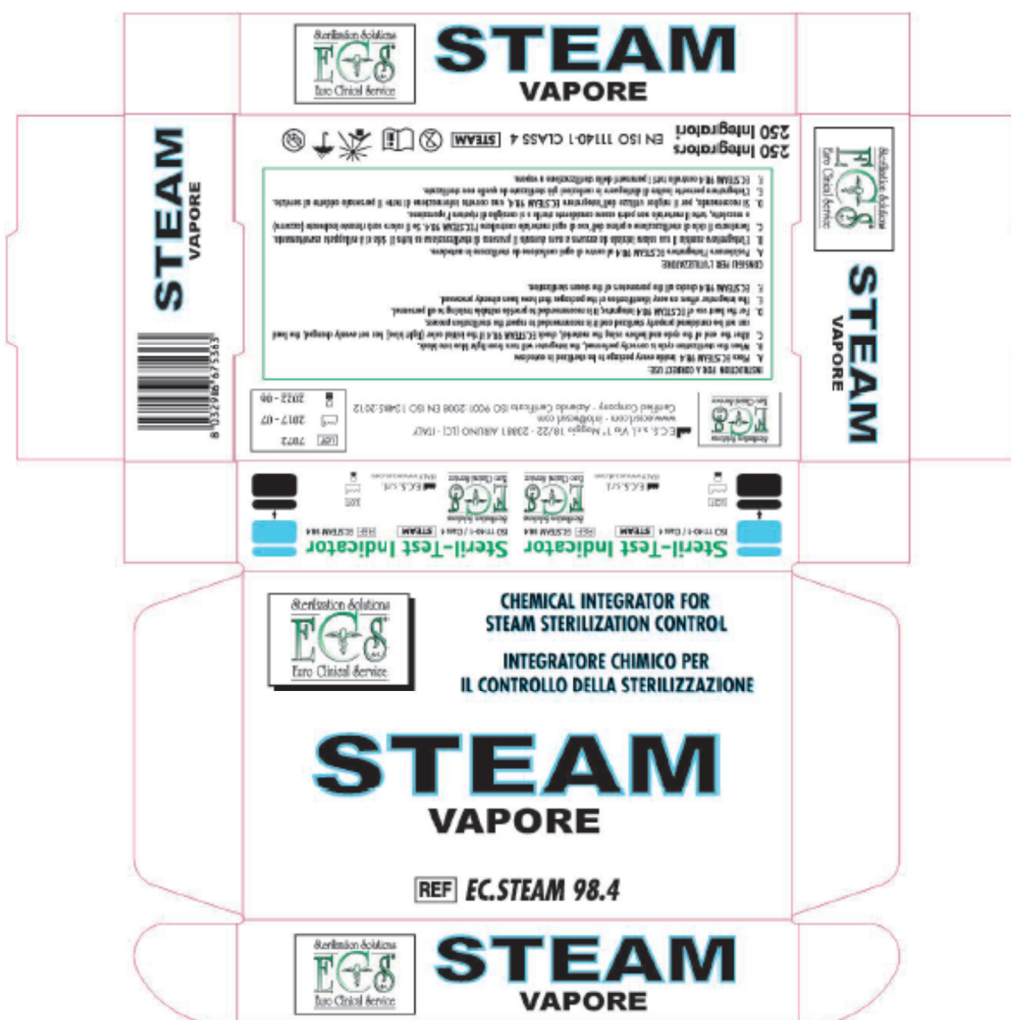
- Not more than 15 minutes at 121 °C
- Not more than 5,3 minutes at 134 °C

The indicator/integrator emulate the biological indicator performance.

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**TEST PROCEDURE**

- Put the integrator EC.STEAM 98.4 in the middle of each packaging to submit to the sterilization in autoclave.
- The Indicator have to change from blue to black during the sterilization process when all the cycle has developed in the right way.
- When the cycle has ended and before the use of each material please check EC. STEAM 98.4. If the color has not changed, all material can't be consider processed and we suggest to repeat the operation.
- We suggest, for a better use of the integrator EC.STEAM 98.4, the right information of all the employed personal.
- The integrator allow to distinguish the already sterilized packaging from the non-sterilized ones.



**PACKAGING IMAGE**

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## PACKAGING

Primary packing: dispenser containing 250 pieces.

Secondary packing: carton containing 20 dispensers.

Each dispenser provides the name of the product and other information, such as: manufacturer name, lot number, production date, deadline and directive compliance.

## STORAGE CONDITIONS

Keep away from humidity: store in fresh and ventilated environments.

Keep away from solar rays or direct light sources.

Use the material in arrival order.

Handle with care.

## WARNINGS

Non-respecting these indications may affect the performance of the product.

EC.STEAM 98.4 integrator is disposable and not reusable.

## PRODUCT SHELF-LIFE

EC.STEAM 98.4 has five years shelf-life from the production date.

The packaging characteristics remain unchanged good conservation, use and storage principles are respected.

## TRACEABILITY

E.C.S. S.r.l. is able to trace all the documentation regarding the product for a period of five years, with production lot printed on the product and on the external packaging.

## DECLARATION OF CONFORMITY

The undersigned E.C.S. S.r.l. having its legal premises in Via Como n.71 – 23883 Brivio (LC), in the name of Mr.IVANO REDAELLI, as CEO

### DECLARES

that the integrator for the control of steam sterilization process EC.STEAM 98.4 (Class 4) is manufactured in compliance with the following directive:

- UNI EN ISO 11140-1:2009 Title: Sterilization of health care products - Chemical indicators - Part 1: General requirements.

E.C.S. S.r.l. also declares that EC.STEAM 98.4 integrator is not a medical device and, therefore, the European Directive 93/42/CEE and further modifications are not applicable, as clearly explained in the document **“MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES Version 1.16 (07-2014)”** that declares what follows **“§7.4. Sterilization indicators”**:

- Background: “The sterilization procedure is monitored routinely by using chemical and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items.”
- Outcome: “Sterilization indicators monitor the performance of the sterilizer. They do not affect the sterilization procedure and only provide additional information to the user. Sterilization indicators do not fulfill either the definition of a medical device laid down in Article 1(2)a of Directive 93/42/EEC or the definition of an accessory laid down in Article 1(2)b of Directive 93/42/EEC as they are not intended specifically to be used together with a device to enable it to be used in accordance with its stated use.”

Brivio, May 2021

E.C.S. S.r.l.