TECHNICAL DATA SHEET **EC.STEAM 98.3-L**	Mod. ST32 EN
	Rev. 10
	May 2021

MANUFACTURER IDENTIFICATION

E.C.S. S.r.l.
Via Como, 71
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PRODUCT DESCRIPTION

EC.STEAM 98.3-L is an integrator used for controlling high STEAM concentration sterilization process and gravitational removal autoclaves, working in all the sterilization cycles with steam at standard reference temperatures of 121 °C/16,5 min. e 134 °C/5,3 min.

The indicator is plasticized in order to preclude the possible ink release on sterilized products. It emulates the identical performance of the biological indicator.

The indicator/integrator will give clear evidence of exposition at saturated STEAM sterilization cycle turning from yellow to black at the following conditions.

- 16,5 minutes at 121 °C
- 5,3 minutes at 134 °C

PACKAGING IMAGE

TEST PROCEDURE

- Place EC.STEAM 98.3-L integrator in the middle of each packaging to expose to autoclave sterilization cycle.
- When the cycle is correctly developed, the indicator must turn from yellow to black during the process.
- Once the sterilization cycle is completed and before using the material, check EC.STEAM 98.3L. If the initial color (yellow) has not evenly changed, all material will not be considered processed and we recommend to repeat the operation.
- It is recommended, for the best use of the EC.STEAM 98.3L integrator, a correct information of all the employed workers.
- The turning ink of the integrator offers an easy and prompt distinction between the packages that have already been sterilized and the non-sterilized ones.
- EC.STEAM 98.3L controls all STEAM sterilization parameters.

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 and deadline, reference cycle, operation temperature and directive compliance.

STORAGE CONDITIONS

Keep far from humidity: store in fresh and dry environment.

Keep away from solar rays and direct line exposition.

Use the material in arrival order.

Handle with care.

WARNINGS

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

EC.STEAM 98.3-L is disposable and not reusable.

PRODUCT SHELF-LIFE

EC.STEAM 98.3L has 5 (five) years shelf-life from production date.

Packaging characteristics remain unaltered if good conservation, use and storage instructions are fully respected.

TRACEABILITY

E.C.S. S.r.l. is able to trace all the documentation regarding the product for a period of 5 (five) years, through the production lot printed on the product and on the external package.

COMPLIANCE TO DIRECTIVES

EC.STEAM 98.3-L is manufactured according to the following norm:

- UNI EN ISO 11140-1:2015 – Class 5 “Sterilization of health care products - Chemical indicators - Part 1: General requirements”.

With regard to the above standard, the firm has commissioned an external and qualified laboratory to perform a specific assessment test (Report N. 11/2015) to confirm the correct operation of the product. The results show a perfect functionality of the product EC STEAM 98.3-L.

TO WHOM IT MAY CONCERN

Brivio, May 2021

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

D E C L A R E S

that control integrator of steam sterilization process EC.STEAM 98.3-L (Class 5) is manufactured in compliance with the following directive:

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

E.C.S. S.r.l. also declares that EC.STEAM 98.3-L integrator is not a medical device and, therefore, the European Directive 93/42/CEE and further modifications as clearly defined in the document: **"MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES Version 1.16 (07-2014)"** that reports what follows the **"§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."*

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