

TECHNICAL DATA SHEET EC.STEAM 98 S	Mod. ST59 EN
	Rev. 4
	May 2021

MANUFACTURER IDENTIFICATION

E.C.S. S.r.l.
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EXTERNAL IMAGE



**INTERNAL SHEET FRONT / BEFORE (YELLOW)
 AND AFTER THE PROCESS (BLACK)**

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Sterilization Solutions		EC. STEAM 98 S	
E.C.S. Euro Clinical Service		STEAM - VAPORE	
134°C/3,5 min.-EN ISO 11140-1, class 2, EN ISO 11140-3 & 11140-4			
RESULT		Date - Data	Cycle - Ciclo
<input type="checkbox"/> ✓	OK	Hospital Ospedale	LOT 7095
<input type="checkbox"/> ✗	NO	Dept. Reparto	2017-10
 Supervisor - Responsabile		Autoclave N°	2022-09
 Operator - Operatore			

INTERNAL SHEET – BACK

Internal sheet presents specific characteristics for its own composition : dimensions are 11,5 x 11,5 cm. and it is composed by a front side printed with a process indicator sensitive to temperature, time and saturated steam and a backside with record sheet and suitable spaces to be filled in by the operator.

PRODUCT DESCRIPTION

The disposable Bowie & Dick test pack EC.STEAM 98 S is composed as follows:

- External packaging: carton box with process indicator for STEAM cycle.
- The inside part is made by two filtering layers of pure pulp paper with a carton with the color indicator for the Bowie & Dick test in the middle.
- The indicator does not release ink since covered by a plastic film.

The packaging of EC.STEAM 98 S grants a constant compactness to the entire inside of the pack, allowing the correct permeation of steam through the paper's pores and not through the possible holes that would be created between the single papers that compose it.

All the material is suitable for medical use.

The test pack has an external process indicator that will turn to grey/black after being processed, in order to identify the already processed packaging from the unprocessed ones.

Bowie Dick test pack EC.STEAM 98 S is suitable for steam sterilizers – big and small sterilizers.

CHARACTERISTICS

The test is designed to check indirectly the ability of the device to put in contact the material to be sterilized with the sterilizing agent (steam). EC.STEAM 98 S, designed for the control of the Bowie & Dick cycle, is suitable for steam sterilization cycles at a temperature of 134° C for 3.5 minutes.

TEST PROCEDURE

- Get sure that the autoclave has performed the warming cycle.
- Place the test into the autoclave with the indicator placed upwards in the centre of the bottom shelf.
- Perform a complete sterilization cycle at 134° C for a sterilization time of 3,5 min.
- At the end of the cycle handle with care: the test pack will be hot, it is recommended to wear protective gloves.
- Remove the pack from the packaging and remove the paper indicator placed at the centre of the pack.

INTERPRETATION OF THE COLOR CHANGE INDICATOR

- If the conditions essential for sterilization are reached, the test will turn from yellow to grey/black confirming that the parameters for which it has been conceived have been respected.
- Any color changing different from grey/black indicates a failure in the correct removal of the air inside the autoclave and that the indispensable conditions for the sterilization haven't been reached; in that case it is recommended to repeat the test using a new kit.



RESULTS' RECORD

- After the use, the sheet indicator is recorded according to sterilization internal protocols.
- The tests' results shall be recorded and available for any control.

ADVANTAGES

- Practical test thanks to its dimensions and sizes.
- Process indicator and data record sheet on the same sheet for an easy reading of results and data recording.
- Necessary for:
 - Failure of air removal
 - Any possible air infiltration
 - Steam overheating

PACKAGING

Primary packaging : boxes containing 20 pieces.

Secondary packaging : carton containing 8 boxes of 20 pieces/each

Each test pack indicates the name of the product, manufacturer's name, lot number, deadline, reference cycle, designed operation temperature, indicator class (class 2) and reference standards.

STORAGE CONDITIONS

Store away from light/heat sources and avoid storage in polluted environments.

Do not store the test pack directly on walls and floor (the product is sensitive to temperature and humidity).

Use the material in order of production date.

Handle with care.

WARNINGS

Failure to respect the storage instructions may affect the performance of the product.
EC.STEAM 98 S is disposable and non-reusable.

HEALTH AND SAFETY

The packaging do not contain any agents or material today considered as toxic.
The products are LATEX AND TOXIC SUBSTANCEES FREE.
The undersigned declines every responsibility regarding the possible following contaminations from air pollution or from another source once the product has been removed from its packaging.

PRODUCT SHELF-LIFE

EC.STEAM 98 S has a 5 (five) years shelf-life from production date.
Characteristics of packaging remain unaltered when good conservation, use and storage instructions are respected.

TRACEABILITY

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

COMPLIANCE TO DIRECTIVES

EC.STEAM 98 S is manufactured according to the following directives:

- UNI EN ISO 11140-1: 2009 “Sterilization of health care products - Chemical indicators - Part 1: General requirements”
- UNI EN ISO 11140 – 3: 2009 “Sterilization of health care products - Chemical indicators – Part 3: class 2 indicators designed for use in the Bowie-Dick type steam penetration test”
- UNI EN ISO 11140 – 4: 2007 “Sterilization of health care products - Chemical indicators - Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration”
- UNI EN ISO 285:2016 Sterilization – Steam Sterilization – Big Sterilizers
- UNI EN 867-5:2004 – Non biological system for sterilization use – Specification for indicator system and for process test device for the performance test of the small sterilizer Type B and Type S

The disposable test pack Bowie & Dick is not a medical device.

With regard to the standards above, the company has commissioned an external and qualified laboratory to perform a specific assessment test (Report N. 01/2015) to confirm the correct operation of the product.

The results show a perfect product functionality of the product EC.STEAM 98 S.

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

DECLARES

that disposable Bowie Dick test code EC.STEAM 98 S is manufactured in compliance with the following directives:

- UNI EN ISO 11140-1: 2009 “Sterilization of health care products - Chemical indicators - Part 1: General requirements”
- UNI EN ISO 11140 – 3: 2009 “Sterilization of health care products - Chemical indicators – Part 3: class 2 indicators designed for use in the Bowie-Dick type steam penetration test”
- UNI EN ISO 11140 – 4: 2007 “Sterilization of health care products - Chemical indicators - Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration”
- UNI EN ISO 285:2016 – Sterilization – Steam Sterilization – Big Sterilization
- UNI EN 867-5:2004 – Non biological system for sterilization use – Specification for indicator system and for test device of process for the performance test of the small sterilizer Type B and Type S

E.C.S. S.r.l. also declares that the disposable Bowie Dick test code EC.STEAM 98 S is not a medical device and, therefore, the European Directive 93/42/CEE and further modifications are not applicable.

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

