TECHNICAL DATA SHEET HELIX TEST KIT CL.6	Mod. ST50 EN
	Rev. 3
	May 2021

MANUFACTURER IDENTIFICATION

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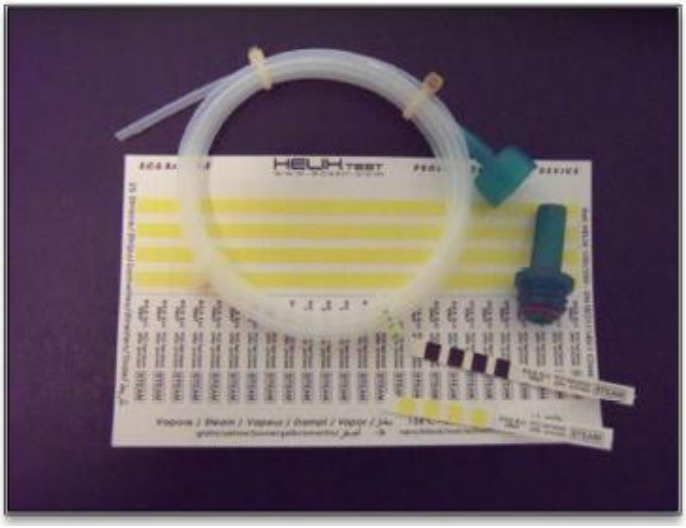
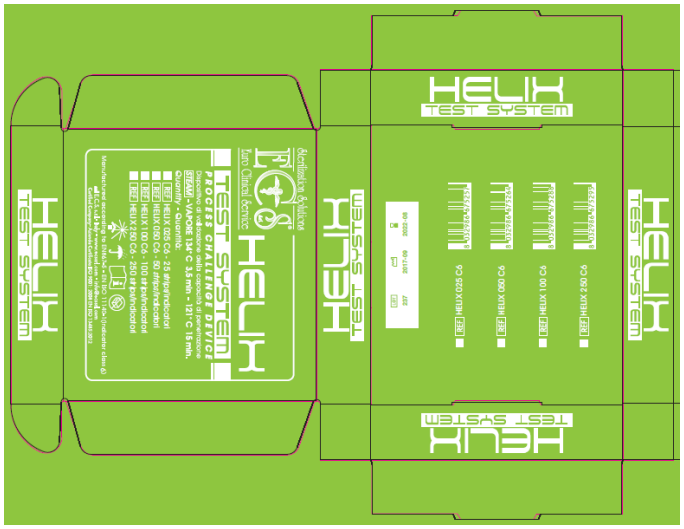


PRODUCT IMAGE



PACKAGING IMAGE

PRODUCT DESCRIPTION

The spiral device HELIX TEST is composed by a PTFE tube, connected to a Moplen hermetic endurance room, preserved by a press-fitted ring to insert and place the specific straps (chemicals indicators in strip).
PTFE and Moplen material is of well-established use in the production of invasive medical devices (at least of class IIa, according to how provided by European Directive 93/42/CEE), such as catheters needles, Huber needles and Tuohy needles and, therefore, they can absolutely be declared conformed according to the annex risks with the possibility of substances release.
In addition, according to the requirements requested by standard UNI EN 867-5, with regard to employed materials, it's clearly exerted that it can be in PTFE or other material (in this case the dimensional characteristics may change, as long as the spiral device ensure the correct functioning). This is showed by E.C.S. S.r.l performed tests in qualifies laboratories. We can confirm that the product responds to dimensional requirements and of materials provided by standard UNI EN 867-05.

The re-use of the device is tested and granted for the strips quantity showed in the appropriate packaging:

- KIT 25 STRIPS
- KIT 50 STRIPS
- KIT 100 STRIPS
- KIT 250 STRIPS

TECHNICAL CHARACTERISTICS

The function of the test is to indirectly check the ability of the device to put in contact the material that has to be sterilized with the sterilizing agent (STEAM).
HELIX TEST, studied for the Helix test cycle control, is predisposed for the following steam sterilization cycles:

- 134 °C for 3,5 min. ca.
- 121 °C for 15 min. ca.

TEST PROCEDURE

- Open the PCD device, separating the stopper from the capsule, where is placed the housing where the PCD turning strips are inserted.
- Bend the strip over the incision. The indicator shall be directed towards the inside.
- Insert the bended strip in the room. The bended side shall be directed towards the outside of the room, where it will be reached by the steam flow.
- Hermetically close the PCD and make sure that the press-fitted ring is correctly placed
- Carry out a complete sterilization cycle.
- At the end of the cycle open the capsule and take out the indicator.

TURNING INTERPRETATION

- If the totality of the air inside the device has been effectively removed, the saturated steam is penetrated inside the tube up to reach the room and the conditions of temperature and time have been respected, the indicator will change from yellow to grey/black, certifying that the parameters for which it has been conceived have been respected.
- Every changing different from the provided grey/black, indicates a non-correct penetration of the steam inside the hollows, synonymous that the indispensible conditions for the sterilization haven't been reached; in this case it is suggested to repeat the test using a new kit.

PACKAGING

Packaging: box of 18 pieces.
Every test shows the name of the product and the following information: manufacturer name, lot number, production date and deadline, reference cycle, temperature of use for which it has been conceived and the reference standards.

STORAGE CONDITIONS

Keep away from light/heat sources and avoid the storage in polluted environments.
When possible, place the packs not at direct contact with floor and walls (the material is sensitive to temperature and humidity).
Use the material in order of production date.
Handle with care.

WARNINGS

The non respect of the storage standards may affect the performance of the product itself.
HELIX TEST is disposable and non-reusable.

PRODUCT SHELF-LIFE

HELIX TEST can be used for 5 (five) years from the production date.
It is compulsory to remember that the storage properties stay unaltered only if the principles of good storage, use and conservation are respected.

ACCOMPLIANCE TO DIRECTIVES

HELIX TEST is produced in accordance to the standards:

- UNI EN ISO 11140-1:2009 Sterilization of health products – Chemicals indicators Part 1: general requirements.
- UNI EN 867-5:2004 Non biological systems for use in sterilizers – specific for indicator systems and test devices of performance tests processes of small sterilizers Type B and Type S.

In accordance to the previous standards, the society has commissioned a qualified laboratory a specified evaluation test (Report n° 05/2015) to confirm the product correct functioning. The results show perfect functionality of the products HELIX TEST – class 6.

TO WHOM IT MAY CONCERN

Brivio, May 2021

The commissioner E.C.S. S.r.l. with legal address at Via Como, 71 – 23883 Brivio (LC) represented by dal Sig. IVANO REDAELLI, in quality of CEO

DECLARES

That the product HELIX TEST is in accordance to the following standards:

- UNI EN ISO 11140-1:2009 Sterilization of health products – Chemical indicators Part 1 : General requirements.
- UNI EN 867-5:2004 Non biological system for use in sterilizers – Specifics for indicator systems and performance test processes devices of small sterilizers of Type B and Type S.

HELIX TEST is not a medical device and therefore doesn't fall under the requirements provided under the European Directive 93/42/CEE and further integrative modifies, as express by the document **"MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES Version 1.16 (07-2014)**" which shows as 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."

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