# **MELAcontrol®**

Process challenge device according EN 867-5 for testing the function of a "Class B" - autoclave



#### What is MELA control®

MELA*control*® is a process challenge control and indicator system consisting of a test body, the so called "helix" and the MELA*control*® test strips. MELA*control*® is designed for the simulation of difficult sterilization conditions, i. e. of long and narrow-bore instruments that are designated as "Hollow A" in European Standard EN 13060. MELA*control*® conforms to European Standard EN 867-5: 2001 and is only useful for "Class B" - autoclaves.

#### What is a "Class B" Autoclave

The European Standard for small steam sterilizers, EN 13060, classifies autoclaves according to their effectiveness into three processes, or classes: "N", "S", and "B". Only a "Class B" autoclave i.e., the class for the most strict requirements, enables reliable sterilization of all kinds of objects in all kinds of wrappings. This is because of the fractionated

pre-vacuum (preliminary air removal by sub-atmospheric pulsing) which this class offers. This applies, for example, in dental work, to handpieces; in surgical areas, to needle holders with insertion closures; in endoscopy, for example, for biopsy forceps with long and narrow hollow spaces; as well as for narrow-bore tubes and instruments designated as "Hollow A" instruments. A "Class B" autoclave, however, is not only the most secure and most reliable solution for all kinds of sterilized objects: it is also optimal for all types of sterilization packages: with individual or multiple packaging, for example, in paper, film, fabric, containers, etc.

## Security by checking

As a component part of your in-surgery quality-assurance measures, MELA*control*® proves that you have satisfied all stipulated sterilization parameters. This means: security for your surgery, and security for your patients.

### What does MELA control® offer

MELA*control*® offers you the possibility, with a minimum of time and expense, of periodically and cost-effectively confirming in your surgery or hospital the performance effectiveness of your "Class B" autoclave. MELA*control*® simulates the most difficult of all sterilization conditions: for example, with Hollow-Body A instruments. Its effectiveness results from its capsule with an indicator strip only at the end of a long, narrow-bore tube. If this process challenge control system has been successfully sterilized — as shown by the change in colour of the MELA*control*® indicator — then you can assume that the entire charge has been successfully sterilized.

## Simple application

The test strip is located in the removable cap of the MELA*control*® test body, the so-called helix. When saturated steam acts sufficiently long on the helix, it shows a colour change. A new test strip is used for every test with MELA*control*® The items included in delivery of the MELA*control*® are the test body (helix), and 250 test strips.

