The European-International standard EN ISO 11140 series exclusively classifies indicator strips which are able to check the efficiency of the sterilizing agent and to control the conditions of the sterilization process, i.e. those indicator strips are only able to check the efficiency of the process at the place where they are positioned.

Many users, even experts, believe that process conditions inside of a sterilization chamber are homogeneous and indicators are therefore able to monitor the efficiency of a sterilization process independently from where they are placed.

During the last 10 years detailed investigations of sterilization processes have proven that encapsulations of air or non-condensable gases in porous loads or hollow instruments hinder the penetration of the sterilization agent like e.g. steam, formaldehyde or ethylene oxide. Therefore it is important to check the sterilization efficiency of the sterilant but also the penetration of the sterilizing agent into all inner surfaces.

To monitor the penetration characteristics of a sterilization process Process Challenge Devices (PCDs) have been developed to simulate the penetration characteristics of real loads: Their general design is described in EN ISO 11140-1 type 2 (see TI 730-044).

There are currently 3 PCD standards as so-called type tests for sterilizers defined:

1. Bowie-Dick-Test European standard for EU steam sterilizers
   - EN 285 7 kg cotton pack
   - EN ISO 11140-4 test procedure for simulation tests
2. Bowie-Dick-Test USA standard for US steam sterilizers
   - AAMI/ANSI ST79 4 kg cotton pack
   - EN ISO 11140-5 test program for simulation packs
3. Helix-Test for EU large and small steam and LTSF sterilizers
   - EN 867-5 with PTFE capsule of 287 µl and PTFE tube 1.5 m x 2 x 3 mm diameter

These indicator systems are only designed for testing sterilizers in the empty chamber and can only be used for monitoring loads in exceptional cases when they represent the worst-case conditions of the load. For routine monitoring, special indicator systems according to EN ISO 11140-1 must be used that represent the worst-case conditions of the load. Appropriate test methods for selection are described in DIN 58921, see also TI 730-093.