Specification and handling of type 2 indicator systems according to EN ISO 11140-1

The standards EN ISO 11140, parts 1, 4, 5 and 6 contain requirements to type 2 indicator systems on the:

a) manufacturer
b) specific test load (PCD)
c) leak test
d) colour change characteristics of the indicator system
e) behaviour in dry heat (140°C; 30 min) for steam CIs
f) material and the dimensions of the indicator system

a) Information of the manufacturer

The following information must be provided in the directions for use, on the indicators themselves or on the packaging label.

- Sterilization process and parameter for which the indicator is suitable
- Use of the symbols according to standard
- Indication of batch number, expiry date, storage information before and after use (temperature and humidity)
- Handling: inserting the indicator strip into the PCD, positioning of the PCD in the sterilizer, safety information, etc.

CE-mark of indicators:
Sterilizers are classified in the medical device directive (MDD) and in the medical device directive (MDR) as „accessory to medical devices“ and therefore are an „accessory“ of the medical device class 2b.
Indicators are accessories to sterilizers and therefore „accessories to accessory of medical devices“ and are therefore no medical device. Accordingly indicators must not carry a CE-mark!

b) Requirements on the specific test load

The test load is called Process Challenge Device (PCD). The requirements for the test load are described in standards and have a significant effect on the characteristics of the test system (e.g. sensitivity for measuring air removal and steam penetration, temperature-time behaviour).

- Physical properties of the test device (specific heat, thermal resistance, etc.).
- The material of the test device must not have a negative influence on the indicator (i.e. biological or chemical indicator strips).
- The material of the test device must not absorb water.

- The material of the test device must be suitable for the intended temperature range.
- The material of the test device must remain dimensionally stable and leak-proof during usage over its whole durability.

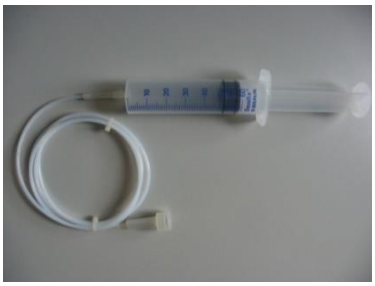
These characteristics must be proven by the manufacturer and documented. It is recommended that these characteristics are verified by an independent accredited testing laboratory.

c) Requirements on the leak tightness

An example of such a test is the leak tightness test for hollow devices according to EN ISO 11140-6 (before: EN 867-5), which can also be easily carried out by any user.

Seal test according to EN ISO 11140-6, paragraph 4.5.2 and
capsule volume test, paragraph 4.5.3

The seal test describes as test setup a PCD which builds up pressure inside using a syringe and an adapter. The closed PCD is put into a water bath (according 4.5.3.3) and into an oil bath (according 4.5.2.2) with maximum sterilization temperature, i.e. 140°C. When pressurized with a syringe, no bubbles must be visible.



d) Requirements on the colour change characteristics of the indicator

- Indication of the sterilization conditions under which the indicator changes colour and the test is passed, i.e. for steam sterilization indication of the necessary temperature-time (F_0) during the presence of water.

e) Requirements on the behaviour in dry heat (140°C; 30 min) for steam CIs

- During absence of water (i.e. in air) at 140°C with a sterilization time of 30 minutes the defined end point (i.e. colour change) must not be reached.

Important information:
Even if the indicators have the same dimensions as those supplied by other manufacturers, chemical indicators react due to their different chemistry (there are sulphur-based, chromium chloride-based and pH-dependent chemical indicators on the market) together

with the PCD extremely different, similar to Bowie Dick simulation packages, where the indicator sheet is only sold together with the paper pack or other PCDs. The change of the free internal volume changes the sensitivity of the whole PCD system significantly.

f) Requirements on the material and the dimensions of the indicator strip for the indicator system

The dimensions and porosity of the indicator influence the free capsule volume. The free capsule volume is very critical modifying the sensitivity.

Therefore a type 2 indicator system always consists of a defined PCD and an indicator strip and the test specifications relate only to this defined combination. If one component is changed, the test characteristics will change dramatically.

Verification of these specifications by an accredited test laboratory

The manufacturer has to specify the characteristics of the whole test system in a certificate of conformity and declare that the test system meets the specifications of a test system in a defined standard. If no original PCDs according to standard are used, equivalence tests must be carried out in a test laboratory to ensure that the alternative PCD system complies with the standard test system.
The manufacturer should be able to provide the laboratory report for these tests on request.

It is recommended to assign an independent accredited testing laboratory with these tests. Attention should be paid:

- that the (accredited) test laboratory must have the necessary test resistometer (so-called „square-wave-generator“) according to ISO 18472, and
- that the scope of the accredited laboratory covers the test method and has the necessary experience to perform these tests.
- that the laboratory has the necessary test instructions and experiences to carry out those tests.

The requirements above are valid correspondingly not only for the Helix-PCD described above but also for all other PCDs, e.g. Bowie-Dick-Test according to EN 285.