	Technical Information	730-175-EN		V02
	According to the validation standard, test devices (PCD) must have a greater penetration challenge than the load	Created	30.11.2020	JM
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The standard EN ISO 14937 - "Sterilization of health care products - General requirements for the characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices" - is often referred to as the "mother standard" because the specific validation standards have been derived from this generally formulated standard (*).

The standard describes in section 8 ("Process definition") that a sterilisation process can be designed with biological (BI, see item 8.3) or chemical indicators (CI, see item 8.4). However, the indicator must then (quote): ***„[...] be placed at positions in product where it has been determined that sterilizing conditions are most difficult to achieve or within a process challenge device (PCD).“*** (end of quote) (**)

The process challenge device (PCD) mentioned above cannot be selected arbitrarily, but in section 8 ("Process definition") point ***8.6.*** specifies (quote): ***„PCDs shall present a challenge equivalent to or greater than that at the position in product where it has been determined that sterilizing conditions are most difficult to achieve.“*** (end of quote) (***)

This PCD, which poses a greater challenge than the loading, must then also be used for routine, i.e. batch monitoring, see section 10 "Routine monitoring and control". There it says in ***10.7.*** (quote): ***„If PCDs are used in routine monitoring and control, they shall comply with 8.6.“*** (end of quote)

Comments:

(*) The specifications of EN ISO 14937 apply to all sterilization processes in which microorganisms are inactivated by physical and/or chemical means (see section 1 "Scope"), i.e. in the same way for steam, formaldehyde, ethylene oxide, hot air and hydrogen peroxide sterilization processes.

(**) A PCD is used to test the access of the sterilant to a difficult (if possible the most difficult) place.

(***) Because a process challenge device (PCD) must relate to the goods to be sterilised, it cannot be built into the steriliser because the manufacturer of the steriliser cannot, of course, "predict" which goods will be sterilised in the unit.