In the standard EN ISO 17665-1 for the validation and routine monitoring of steam sterilization processes several times the use of PCDs is described. PCDs have to be used, if the most difficult locations for steam penetration and sterility cannot be determined by thermal measurements and/or biological or chemical indicators. See the following paragraphs in the standard referring to a PCD:

6.1 *Saturated steam processes*

In addition to the requirements in 6.1.1, the specification for a saturated steam sterilization process in which the steam admitted to the sterilizer is the sterilant, shall include:

c) where the product family(ies) identified in 6.1.1 c) consist of materials known to restrict the penetration of steam by virtue of their design or load configuration or, unless otherwise justified, a description of the steam penetration test used to verify that the level of non-condensable gases carried into the sterilizer chamber in the steam supply, by air leakage into the chamber during periods of vacuum or remaining as a result of an inadequate air removal stage of the operating cycle, does not prevent the presence of saturated steam on the surfaces to be sterilized;

6.2.5 *Means shall be provided to ensure that failure to attain specific process parameters does not lead to an ineffective sterilization process appearing to be effective.*

7.5 *If a process challenge device (PCD) is identified as a challenge that can be used to represent the product and its packaging system, it shall be defined.*

8.9 *If a PCD is to be used to assess the efficiency of the specified sterilization process for processing the product identified in Clause 7, the validity of the PCD, test methodology(ies) and acceptance criteria shall be established and documented.*

9.4.4 *For each of the following, studies shall establish:*
g) the response of the PCD, when used;

9.5.2 *A sterilization process specification, including the process parameters and their tolerances, shall be confirmed. The specification shall include the criteria for designating the sterilization process used for a particular sterilizer load as confirming, and shall document at least the following:*
a) the product family(ies) that can be processed;

12.1 *Demonstration of continued effectiveness*
12.1.6 *If the sterilization process relies on the removal of air from the sterilizer chamber in order to achieve rapid and even penetration of steam in the sterilizer load, a steam penetration test shall be carried out each day before the sterilizer is used.*
The steam penetration test is carried out using a device having a defined challenge to air removal and steam penetration for the process. For industrial applications, if the saturated steam process uses consistent, defined sterilization loads known not to inhibit the penetration of steam,

alternative methods may be used based on specific physical measurements and a risk assessment of the likelihood of process failure.

C.2.2 *A challenge to the sterilization process comprising a known number of microorganisms with known resistance to the sterilizing agent should be created by either:*
a) placing biological indicators within the product at position(s) or representative of positions where sterilizing conditions are most difficult to achieve, or

D.2.2 *A challenge to the sterilization process should be created by either:*
a) placing biological indicators within the product at position(s) or representative of positions where sterilizing conditions are most difficult to achieve, or
b) inoculating the product with reference microorganisms at position(s) within the product where sterilizing conditions are most difficult to achieve.

D.2.3 *The challenge should be packaged the same as routinely product and included within the sterilization load in the location where it is most difficult to achieve sterilizing conditions.*

The corresponding PCDs have to secure by previous validation that they represent the medical device or rather the complete load.

Without these systems the validation and routine monitoring of complex medical devices can only be determined by microbiologic procedures (direct inoculation and evaluation). This method can only be used for basic testing, but not for routine monitoring.

Definitions of the process test system (PCD)

PCD	= Process Challenge Device: General term for a test device without special definition what it represents
MDS	= Medical Device Simulator: Simulates a certain medical device. It has to be tested in the packaging corresponding to the medical device.
BMS	= Batch Monitoring System: Represents a complete load in ist worst-case situation. It is used without packaging at the most difficult location of the sterilizer (in steam sterilizers in the bottom area near the door).