The standards for large (EN 285) and small steam sterilizers (EN 13060) use type tests to prove that the air removal and steam penetration requirements are fulfilled. These type-tests, e.g. the Bowie-Dick-Test for large sterilizers or the hollow load helix-test according to EN 867-5 (new: EN ISO 11140-6) for large and small sterilizers do not provide any information, if the sterilizer can effectively sterilize the load configuration the user wants to process. Sterilizer manufacturers do not know in advance which products are sterilized later on or if those products are sterilizable at all depending on their construction.

Therefore test systems, called Process Challenge Devices (PCDs) have been developed which are validated using a defined load configuration but not a sterilizer specification or type test as a reference. In 2011 the German standard DIN 58921 has been published how to validate such PCDs with the title:
„Test method to demonstrate the suitability of a process challenge device in simulating medical devices during steam sterilization — Medical device simulator testing". This standard has been translated into English.

If a test system is validated according to a single medical device, it is called a Medical Device Simulator (MDS). Alternatively a whole load configuration can be used as a reference which is called batch monitoring system (BMS) and can monitor a whole load.

The introduction and scope of this new standard is copied:

> **Introduction**
>
> Steam sterilization is a so-called „special process" where the result can not be proven without a destructive test. To show the effectiveness of such processes, a comprehensive monitoring of parameters influencing the process is necessary. From compliance of those parameters it is concluded that a reproducible effect of the process exists.
>
> The Medizinproduktegesetz (MPG / German medical devices act), die Medizinprodukte-Betreiberverordnung (MPBetreibV / Medical Devices Operator Ordinance), guidelines 1) and DIN EN ISO 17665-1 require or support reprocessing with validated processes.
>
> The information on reprocessing for medical devices to be provided by the manufacturer are given in DIN EN ISO 17664.
>
> Validation is a documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield results or products complying with predetermined specification. This proof is largely based on examination of critical physical values (process relevant parameter) in the sterilizer chamber and at critical locations of medical devices, e.g. locations with hindered steam penetration or delayed temperature increase. For medical devices with special characteristics and where proof can not be generated by physical methods, biological and if applicable non-biological indicators need to be used (see DIN EN ISO 17665-1.2006-11, 9.4.5 and Annex D).
>
> In the routine of public health care this requirement hits difficulties, e.g. limited availability of the medical device during validation, high level of required technical testing, long time period until evaluation of results. A relevant portion of those difficulties disappear, if the necessary testing is not performed on the medical device itself, but on surrogate devices, test devices or on medical device simulators (MDS) for the purpose of this standard.

Information on the use of test devices instead of a medical device can be found e.g. in DIN EN ISO 17665- 1:2006-11, 7.5.

However this way of verification is only valid if it can be secured that the test device represents a higher challenge to air removal and steam penetration than the actual medical device itself / the product family (see DIN EN ISO 17665-1:2006-11, 3.38).

This standard describes the modus operandi to proof that the test device shows corresponding requirements against the sterilization process. It may be assumed that a successful testing with a test device instead of the actual medical device during validation confirms the effectiveness of the process on real sterilizer load items.

1 Scope

This standard specifies a test method with which can be demonstrated that a medical device simulator for use in sterilization processes of large steam sterilizers complying with DIN EN 285 and of small steam sterilizers complying with DIN EN 13060 (Type B Cycle) has a greater level of difficulty in achieving sterilization conditions in terms of air removal and steam penetration than the simulated medical device itself. A medical device simulator (MDS) qualified according to this standard is only valid for the examined medical device (MD).

NOTE 1 Attention is drawn to the fact that similar looking medical devices can have different internal constructions. These differences can have an influence on the air removal and steam penetration capabilities. This can have an influence on the validity of the MDS.

NOTE 2 A medical device simulator for which such evidence was provided, can be used during validation to present the original medical device only in terms of air removal and steam penetration.

NOTE 3 A medical device simulator, qualified on the basis of this standard, can also be used for the development of sterilization processes.

NOTE 4 A medical device simulator qualified according to this standard is not necessarily suitable to represent other requirements of the relevant medical device (see 8.2).

This standard neither specifies requirements for the design of medical device simulators, nor material requirements for medical device simulators.

Already the introduction of this standard demonstrates that load-related test systems are developed and judged completely independent from the used sterilizer program.

GKE offers with the Ophthal-BMS, the Dental-BMS and the Tattoo-BMS the first load-related test-systems worldwide whose characteristics exclusively represent the goods to be sterilized – and not to the sterilizer program used.