

	Technical Information	730-088-EN		V04
	Design of all GKE Steri-Record® Compact Process Challenge Devices (C-PCDs) to check the efficacy of sterilization processes	Created	20.11.2007	UK
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GKE produces several C-PCDs which are calibrated against type tests of steam sterilizers (Bowie-Dick-Test of EN 285, Hollow load Helix-Test according to EN 867-5, new: EN ISO 11140-6) and so-called Batch Monitoring Systems (BMS) which are calibrated according a defined load configuration.

All C-PCDs use an internationally patented design which consists of the following components:

1. The outside plastic case is made of highly mechanically thermostable (up to 190 °C), biocompatible plastic material with varying active internal volume of 10 - 100 ml.
2. Inside the plastic case there is the opening of a stainless steel coil of various diameters (1-5 mm) and lengths (10 – 100 cm) with the open end connected to the inner volume of the case.
3. The other end of the stainless steel tube is connected to a capsule of 0,1 - 5 ml.
4. The capsule contains a chemical or biological sterilization monitoring indicator which must have a defined carrier volume, porosity and chemical or biological nature to detect non-condensable gases (NCG).



The combination of those 4 connected design elements allows by modifying each of them to produce a variety of different test devices especially tailored to sterilizer type tests or to check special load configurations. This unique design allows to simulate the sterilant penetration characteristic of packed solid instruments, hollow devices and even porous loads, without using porous components using the large volumes as an entrance in the PCD.

All CPDs are tested by an independent test laboratory which is especially accredited to test the efficacy of sterilization processes, test devices, indicators and the sterilizability of medical devices.