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	Labeling of GKE indicators for use in PCD systems	Created	11.03.2004	UK
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PCD (Process Challenge Device = PCD) systems are designed to monitor extreme small amounts of non-condensable gases (NCG), like air or CO₂ coming from insufficient air removal, leaks in sterilizers, pneumatically activated door seals or non-condensable gases in steam. Very small amounts of NCG can jeopardize the sterilization inside of complex instrumentation like minimal invasive surgical (MIS-) instruments.

To monitor such small amounts of NCG - extreme small volumes inside of the PCDs are necessary. This requirement has the consequence that the indicators of the PCD system must be very tiny as well. The small surface at the small indicator size does not allow to print text like sterilization process, batch number or expiry date onto – in comparison to traditional indicators with much bigger surface areas being used inside or outside of packs.

The International standard EN ISO 11140-1 requires for chemical indicators to mention the manufacturer's address, the batch number, the expiry date and the description of the sterilization process to be used for. In paragraph 5.4 this standard allows to put this amount of information onto the directions for use and/or the packaging of the indicators if there is not enough space to put it on the indicator itself.

The GKE indicators are primary packaged in a box of cardboard including name, expiry date, article number and batch number. Moreover they are secondary packaged in a poly-bag containing the batch number, expiry date and manufacturer's name as well and conforms with EN ISO 11140-1.

GKE is certified according to EN ISO 13485. The quality management system certifies the design, manufacturing and distribution of biological and chemical indicators and documentation materials and any items that are medical devices. Our products are manufactured according to the above standard with detailed manufacturing specifications and they have to pass a quality control system to verify that the packaged products conform to the defined specifications.