

# DIRECTIONS FOR USE



## GKE Steri-Record® Bio-Process Challenge Devices (Bio-C-PCD®)

Art.-No.*	Product code	PCD-Version**	Penetration characteristics tested in steam sterilization processes***	Use for recommended Sterilization Process****			
				Steam	EO	LTSF	VHPO
300-031	B-PM-OCPCD-0	oval	minimal requirements	x	—	—	x
300-032	B-PM-RCPCD-0	round		x	—	—	x
300-033	B-PM-OCPCD-1	oval	very low requirements	x	—	—	x
300-034	B-PM-RCPCD-1	round		x	—	—	x
300-035	B-PM-OCPCD-2	oval	low requirements	x	—	—	x
300-036	B-PM-RCPCD-2	round		x	—	—	x
300-037	B-PM-OCPCD-3	oval	less difficult than Hollow load test according to EN 867-5	x	—	x	x
300-038	B-PM-RCPCD-3	round		x	—	x	x
300-039	B-PM-OCPCD-4	oval	equal to Hollow load test according to EN 867-5	x	x	x	To be tested
300-040	B-PM-RCPCD-4	round		x	x	x	
300-041	B-PM-RCPCD-5	round	more difficult than Hollow load test according to EN 867-5 (High Demand Hollow)	x	x	x	
300-042	B-PM-RCPCD-6	round	More difficult than Hollow load test according to EN 867-5 (Very High Demand Hollow)	x	x	To be tested	
300-028	B-E-PM-HPCD	Helix-PCD	EO Type test according to EN 1422:2009	—	x	—	—

(\*) To all article numbers a 3-digit alpha code is added. The additional letter code refers to the language and/or customized and plug version. It is only added on the outside label, the inside of the pack is identical to the article numbers on the above tables.

(\*\*) Round versions are recommended for large and oval versions for small sterilizers.

(\*\*\*) PCDs used for routine monitoring need to be validated representing the worst -case load configuration using the test method DIN 58921.

(\*\*\*\*) The table shows recommendations, however the PCDs have to be tested if the sterilizer is able to penetrate the PCD.

### Application

The GKE Steri-Record® Bio-Compact Process Challenge Devices (Bio-C-PCD®) can be used with all GKE Mini-Bio-Plus self-contained biological indicators (SCBI) for validation and routine monitoring of steam, ethylene oxide, formaldehyde and hydrogen peroxide/plasma sterilization processes. After sterilization the SCBIs can be incubated by the user without a microbiological laboratory.

All SCBIs are especially designed to be used inside a GKE Bio-C-PCD®. Seven Bio-C-PCD®s with different air removal characteristics are available. The sensitivity of these Bio-C-PCD®s can be selected to simulate the load penetration characteristics. The validation of the Bio-C-PCD® according to the load can be achieved by using the test method described in DIN 58921. GKE Bio-C-PCD®s can be used in all four sterilization processes mentioned above, if the correct SCBI and PCD is selected.

There are various hydrogen peroxide/plasma sterilization processes in the market with different penetration and kill kinetics characteristics of the sterilization agent. Depending on the process used and on the load configuration an appropriate Bio-C-PCD® and H<sub>2</sub>O<sub>2</sub>-SCBI should be selected.

### Product Description

The specially designed and patented GKE Steri-Record® Bio-C-PCD® construction consists of a large internal volume with a stainless steel tubing system inside and a minimal capsule volume at the closed end. It can only be used with specially designed Mini-Bio-Plus SCBIs.

The combination of a Bio-C-PCD® and a GKE-Mini-Bio-Plus SCBI is a type 2 indicator system according to EN ISO 11140-1. Conventional SCBIs cannot be used because of lower sensitivity for air removal and sterilant penetration inside the PCD.

Round versions are recommended for large and oval versions for small sterilizers but both versions have the same penetration characteristics.

## Product Description

Bio-C-PCD®s with SCBIs inside can simulate porous loads and hollow devices simultaneously. A special Bio-C-PCD® to simulate the hollow load test described in EN 867-5 is available as one of them.

Additional Bio-C-PCD®s are available to simulate different load configurations and shall be validated once with the test method, described in DIN 58921.

## Selection of the correct GKE Bio-C-PCD®

GKE offers different Bio-C-PCD®s which have to be selected depending on the sterilizer and load, air removal and sterilant penetration characteristics. Use the following procedure:

1. Select a number of PCDs which shall be tested together in the sterilizer.
2. Open the caps of the selected PCDs and make sure the black seal ring in the screw cap is in good condition.
3. Number the SCBI on the label with the number of the PCD and place each SCBI into one Bio-C-PCD® with the same number and close the cap. The number of the Bio-C-PCD® is marked on the green outside plastic case.
4. Place all Bio-C-PCD®s together on a tray in the lower section of the empty sterilizer or together with the load.
5. Run the sterilization program.
6. On completion of the cycle remove all Bio-C-PCD®s carefully.
7. After cooling down remove the Mini-Bio-Plus SCBI from the Bio-C-PCD®. For details please see directions for use for Mini-Bio-Plus SCBIs and analyse the results.
8. Select the Bio-C-PCD® with the highest number that has been successfully penetrated (without colour change of the liquid growth medium). This Bio-C-PCD® can be used for routine monitoring only if the Bio-C-PCD® has higher penetration characteristics than the most difficult instrument in the load. In case of doubt the procedure in the standard DIN 58921 should be applied to validate the Bio-C-PCD® against the load.

## Handling Information for routine monitoring with the selected Bio-C-PCD®

1. Open the cap of the selected Bio-C-PCD® for routine monitoring and make sure the black seal ring in the screw cap is in good condition.
2. Place a Mini-Bio-Plus SCBI into the selected Bio-C-PCD® and tighten the cap.
3. Place the Bio-C-PCD® in the lower area of the sterilizer on a tray at 2 - 5 cm height to prevent condensate entering the PCD.
4. Run the sterilization program.
5. On completion of the cycle remove the Bio-C-PCD® carefully.
6. After cooling down, remove the Mini-Bio-Plus SCBI and incubate.

For details please see directions for use for Mini-Bio-Plus SCBIs.

## Maintenance Information for Bio-C-PCD®

All Bio-C-PCD®s contain a tubing system made of stainless steel and can be used for an unlimited number of cycles. There is no preventive maintenance necessary. The seal ring in the cap needs to be exchanged after approximately 500 – 1.000 cycles and the exchange should be documented with date and responsible person in the table below or alternatively in external operating instructions.

Each Bio-C-PCD® contains 5 black seal rings for replacement:

1. Remove the black seal ring in the cap with a pointed object (e.g. screw driver, needle etc.)
2. Insert a new seal ring in the cap in the right position.

If a SCBI is too difficult to remove from the Bio-C-PCD®, please check that no glue residues from the SCBI label remain in the PCD. Please use benzine for cleaning.

## Safety Precautions

1. Bio-C-PCD® and Mini-Bio-Plus SCBIs are closely adjusted to achieve the required sensitivity of the type 2 indicator system. If the test device is used with other SCBIs or PCDs, GKE cannot guarantee proper results.
2. If the open end of the Bio-C-PCD®s is not in lowest position during sterilization hot condensate may be collected inside and may come out of the Bio-C-PCD® during removal from the sterilizer burning your fingers.

For further technical details please contact your local dealer or the GKE application laboratory. We will assist you with any technical questions. Also visit our website [www.gke.eu](http://www.gke.eu) for more information.