



# Let Us Guide You

ESSENTIAL INDICATORS, PCD, AND ACCESSORIES FOR MONITORING  
OF CLEANING, DISINFECTION, AND STERILIZATION PROCESSES

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# Mesa Germany

## EXCELLENCE IN CLEANING, DISINFECTION AND STERILIZATION MONITORING

Mesa Germany, a subsidiary of MesaLabs, Inc. operates two production sites in Germany - in Waldems (near Frankfurt) and Munich. The company specializes in manufacturing biological and chemical indicators for monitoring cleaning, disinfection, and sterilization processes. Additionally, Mesa Germany develops process challenge devices to ensure effective process monitoring.

Mesa Germany serves the healthcare sector directly in Germany and worldwide through trained distributors. GKE is the brand for all healthcare products.

Both production facilities are certified according to EN ISO 13485 and ISO 9001 (Munich), ensuring the highest quality standards in manufacturing and process monitoring.

This product guide includes all products, starting with cleaning monitoring, followed by disinfection and sterilization. For sterilization monitoring, products are offered for steam, hydrogen peroxide, formaldehyde, ethylene oxide, and dry heat.



Munich, Germany



Waldems, Germany

## Cleaning Process Monitoring Indicators and Cleaning Indicators

Cleaning process monitoring indicators (CPI) and cleaning indicators assess cleaning efficiency and reliability in sensitive areas such as healthcare, pharmaceuticals, and food processing.

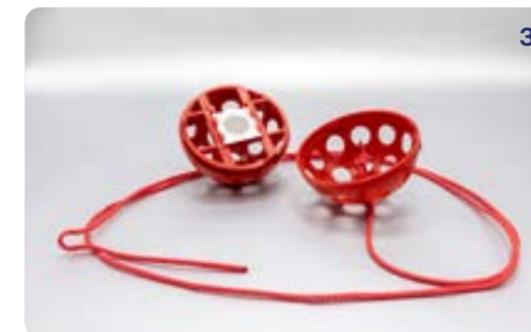
CPI evaluate the entire cleaning cycle by verifying parameters such as time, temperature, chemical concentration, and mechanical force, ensuring process stability and reproducibility.

Cleaning indicators specifically test cleaning effectiveness using standardized test soils that simulate real contamination, with soil removal demonstrating success.



Holder for Cleaning Process Indicators

Art. No.	Product Code	Content	Qty	Photo
800-102	W-PHO	Plastic holder	10	1
800-111	W-HF-PCD	Hollow Flow PCD	1	2
800-130	W-LA-CHECK	Laundry Check Ball	1	3



### Cleaning Process Monitoring Indicators (CPI) for Washer Disinfectors

The indicators are available with different wash-off characteristics. The indicator that has been washed off at the latest, should be used to monitor the cleaning process. The suitable indicator can be selected during a test run.

Art. No.	Product Code	Color	Qty
810-000	W-CPI-O	Orange	64
810-001	W-CPI-O	Orange	160
810-101	W-CPI-Y	Yellow	160
810-102	W-CPI-Y	Yellow	480
810-103	W-CPI-Y	Yellow	960
810-201	W-CPI-G	Green	160
810-202	W-CPI-G	Green	480
810-203	W-CPI-G	Green	960
810-301	W-CPI-B	Blue	160
810-302	W-CPI-B	Blue	480
810-303	W-CPI-B	Blue	960
810-351	W-CPI-P	Purple	160
810-352	W-CPI-P	Purple	480
810-353	W-CPI-P	Purple	960
810-401	W-CPI-R	Red	160
810-402	W-CPI-R	Red	480
810-403	W-CPI-R	Red	960
810-901	W-MC-CPI	Green, Blue, Red	160
810-902	W-MC-CPI	Green, Blue, Red	480
810-903	W-MC-CPI	Green, Blue, Red	960



### Cleaning Process Monitoring Indicators for Ultrasonic Baths

The indicator is placed vertically or horizontally with the holder in the liquid to test the cleaning efficiency.

Art. No.	Product Code	Color	Qty
810-111	W-U-CPI-Y	Yellow	40
810-112	W-U-CPI-Y	Yellow	120
810-211	W-U-CPI-G	Green	40
810-212	W-U-CPI-G	Green	120
810-311	W-U-CPI-B	Blue	40
810-312	W-U-CPI-B	Blue	120
810-411	W-U-CPI-R	Red	40
810-412	W-U-CPI-R	Red	120



### Ultrasonic Baths Cleaning Indicator Holders

Made of stainless steel. Available with 3 different heights to place the indicator in the volume.

Art. No.	Product Code	Content	Qty
800-115	W-U-HO-7	Holder 7 cm height	1
800-116	W-U-HO-20	Holder 20 cm height	1
800-117	W-U-HO-40	Holder 40 cm height	1



### Cleaning RI-ENDO-SET

Set for visual and protein-analytical routine monitoring and validation of cleaning efficacy in endoscope washer disinfectors according to ISO 15883 and German "guideline for validation of endoscope washer disinfectors".

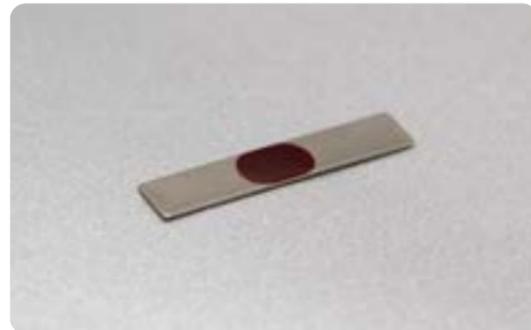
Art. No.	Content
RI-52010-ENDO-SET	50x RI 1x PCD for flexible endoscopes



### Cleaning indicator RI

Cleaning indicator for visual and protein-analytical routine monitoring and validation of cleaning efficacy in washer disinfectors (WD) according to ISO 15883. Together with PCDs the indicator can be used for the simulation of standard instruments, MIS instruments, Crile clamps / narrow gaps and endoscopes (channel / outer surface) and in ultrasonic baths.

Art. No.	Qty
RI-52002	50



### PCD for flexible endoscopes

Process challenge device (PCD) according to EN ISO 15883 (flow PCD, open on both sides), diameter: 2 mm, length: 2000 mm, for simulating endoscopes in washer disinfectors. Use with RI.

Art. No.	Material	Qty
PM-RIBI-2-PC	Polypropylene	1



### Cleaning Indicator RI-SET

Set for visual and protein-analytical routine monitoring and validation of cleaning efficacy in washer disinfectors according to ISO 15883.

Art. No.	Content
RI-52006-SET	50x RI 1x PCD for standard instruments (PP) 1x PCD for narrow, gaps (PP) 1x PCD for MIS instruments (PC)



### PCD for MIS-Instruments

Process challenge device, (Flow-PCD open on both sides) made for simulation of MIS instruments in washer disinfectors. Use with RI.

Art. No.	Material	Qty
RI-52004-PMIC-PC	Polypropylene	1



### PCD for Simulating Narrow Gaps

Process challenge device made for simulation of Crile clamp / narrow gaps in washer disinfectors.

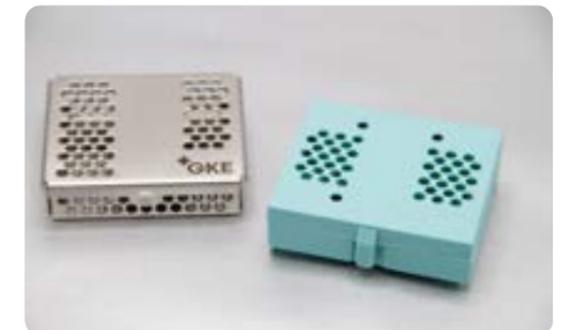
Art. No.	Material	Qty
RI-52003-PPB	Polypropylene	5



### PCD for Simulating Surgical Instruments

Process challenge device for simulation of standard instruments made of stainless steel (V2A) in washer disinfectors or synthetic material (PP) for simulation of standard instruments in washer disinfectors or ultrasonic baths.

Art. No.	Material	Qty
RI-52003-V2A	Stainless steel (V2A)	1
RI-520063-PPY	Polypropylene	5



### MiniTray for fixing PCDs

MiniTray for fixing the PCDs RI-52003-PPY and RI-52003-PPB.

Art. No.	Material	Qty
RI-52009	Stainless steel (V2A)	1



### Crile clamp

Test specimen with test soil according to German DGSV-Guideline for visual and analytical monitoring of cleaning efficacy in washer disinfectors.

Art. No.	Qty
PK-PET-K	5



## Disinfection

Biological indicators are used to verify the effectiveness of disinfection processes. They help ensure that critical parameters such as time, temperature, chemical concentration, and exposure have been adequately met to eliminate or reduce microorganisms to a safe level. These indicators are commonly used in healthcare, laboratories, and industries requiring high hygiene standards. By providing a measurable way to validate disinfection processes, they play a vital role in maintaining safety and preventing contamination.

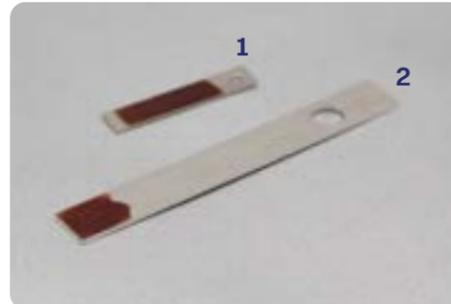


### Biological indicator for automatic reprocessing procedures of flexible endoscopes

Biological indicator for biological and protein-analytical validation and routine monitoring of cleaning & disinfection processes for endoscope reprocessing. The indicator complies with the requirements of ISO 15883. Together with PCDs the indicator is used for testing the cleaning efficacy and disinfection in endoscope channels.

Test organism: *Enterococcus faecium*

Art. No.	Dimension	Application	Population	MOQ
BI-EF-14051	30 x 6 x 0.5 mm	in PCD	10E9	5
BI-EN-14001	70 x 9 x 1 mm	in chamber	10E9	5



### PCD for flexible endoscopes

Process challenge device (PCD) according to EN ISO 15883 (flow PCD, open on both sides), diameter: 2 mm, length: 2000 mm, for simulating endoscopes in washer disinfectors. Use with BI-EF.

Art. No.	Material	Application	Qty
PM-RIBI-2-PC	Teflon (PTFE)	Endoscope WD	1



### Biological indicator for Washer-Disinfectors (WD)

Biological indicator for the validation and the routine control of cleaning and disinfection processes, qualitative analysis.

Test organism: *Enterococcus faecium*

Art. No.	Dimension	Application	Pop	MOQ
BI-BWA-16001	160x9x1 mm	Medical bed frames, contains	10E5	10
BI-GSA-17001	160x9x1 mm	Medical dishwashers	10E5	10
BI-FS-18001	160x9x1 mm	Bedpan washers	10E5	10
BI-OPS-19001	160x9x1 mm	Surgical clogs	10E5	10



### Biological indicator for testing Washer-Disinfectors (WD)

Biological indicator for the validation and the routine control of cleaning and disinfection processes, quantitative analysis.

Test organism: *Enterococcus faecium*

Art. No.	Dimension	Application	Pop	MOQ
BI-RAM 10.7*	160x9x1 mm	Medical bed frames, contains	10E7	50
BI-RAMS 10.7	160x9x1 mm	Dish washers, Bedpan washers	10E7	50

\* not in stock available, on demand.



### Biological indicator for Textile Washers

Biological indicator for biological validation and routine monitoring of cleaning processes for textiles. The biological indicator meets the requirements of RKI, VAH, DGHM and ISO 15883.

Test organism: *Enterococcus faecium*

Art. No.	Application	Pop	Qty
BI-TEX-15001-10	textile	10E7	10



### Biological indicator for Thermal Disinfection

Biological indicator for biological validation and routine monitoring of thermal disinfection processes at a temperature of 70 °C - 95 °C. The biological indicator meets the requirements of ISO 15883.

Test organism: *Enterococcus faecium*

Art. No.	Population	Qty
BI-TD-12001-10	10E7	10



### Biological indicator for Chemo-Thermal Disinfection

Biological indicator for biological validation and routine monitoring of chemo-thermal disinfection processes at a temperature of 55 °C - < 70 °C. The biological indicator meets the requirements of ISO 15883.

Test organism: *Enterococcus faecium*

Art. No.	Population	Qty
BI-CTD-13001-10	10E5	10



### Biological Indicator for Disinfection of liquids

Biological indicator for biological validation and routine monitoring of disinfection processes for liquids. The biological indicator meets the requirements of DIN 58949-4. Only permitted for disinfection processes with thermally controlled cooling.

Test organism: *Bacillus atrophaeus*

Art. Nr.	Application	Population	Qty
BI-FLDS-10	liquids	10E5	10



### Biological indicator for Steam Disinfection 75 °C

Biological indicator according to DIN 58949-4, for biological validation and routine monitoring of steam disinfection processes at 75 °C - 20 min and 105 °C - 1 min.

Test organism: *Enterococcus faecium*

Art. No.	Population	Application	Qty
BI-DE-11001-50	10E6	eg. mattresses	50



### Biological indicator for Steam Disinfection 105 °C

Biological indicator according to DIN 58949-4, for biological validation and routine monitoring of steam disinfection processes at 105 °C - 5 min.

Test organism: *Bacillus atrophaeus*

Art. No.	Population	Qty
BI-DS-10001-50	10E5	50

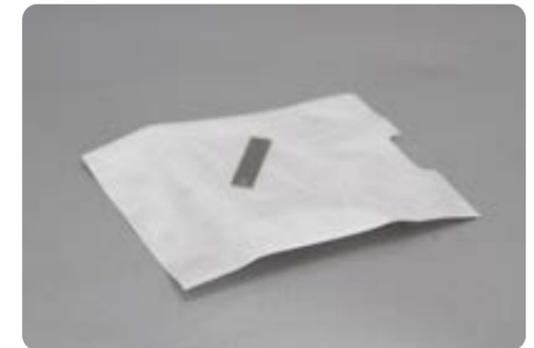


### Biological indicator H<sub>2</sub>O<sub>2</sub> decontamination

Biological indicator according to ISO 14937, for decontamination processes with H<sub>2</sub>O<sub>2</sub>.

Test organism: *Geobacillus stearothermophilus*

Art. No.	Population	Qty
BI-OX-2200-6-V4A-10	10E6	10
BI-OX-2200-6-V4A-50	10E6	50



# STEAM

## Indicators

### FOR STEAM STERILIZATION

Steam sterilization indicators are tools used to verify the effectiveness of the sterilization process in healthcare.

**Chemical Indicators:** These are external or internal indicators, such as strips or tapes, that change color or form when exposed to specific sterilization parameters.

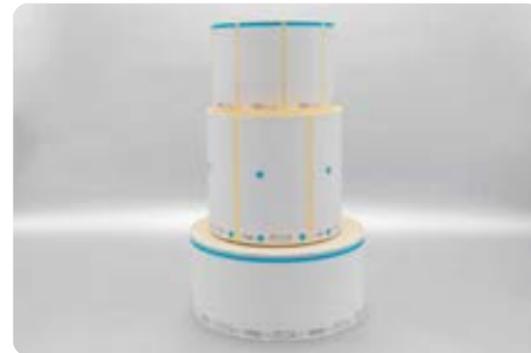
**Biological Indicators (BI)** contain highly resistant bacterial spores. After sterilization, they are incubated to confirm the absence of microbial growth, ensuring complete sterilization. Using a combination of these indicators ensures a high level of confidence in the sterilization process.



#### TYPE 1 PROCESS INDICATORS

Type 1 process indicators show if a sterilization package has undergone a sterilization process but do not confirm its quality. Adhesive labels can be applied to plastic, paper, or (non-)woven materials.

- Single adhesive labels.
- Double adhesive labels.
- Customized design printing (MOQ required).
- To be labeled with information for tracking and logistics.



#### Plastic inserts

free of charge, for smaller core diameter of label rolls. The inserts are re-usable.

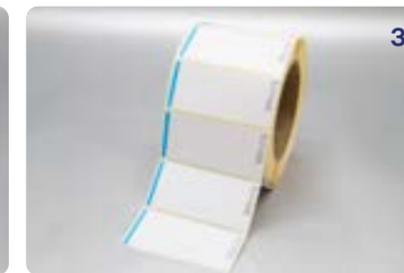
Art. No.	Product Code	Description	Qty
000-332	Reducing insert	3" to 2"	2
000-315	Reducing insert	3" to 1.5"	2
000-331	Reducing insert	3" to 1"	2
000-221	Reducing insert	2" to 1"	2

All GKE process indicators for steam sterilization processes change their color from blue to brown/black as shown:



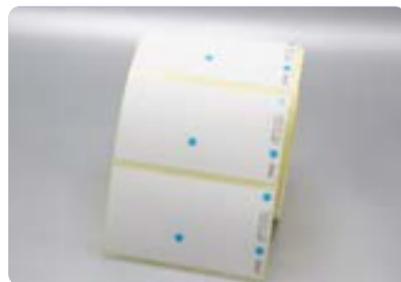
#### Endless labels to be used in printers with cutting device, double self-adhesive

Art. No.	Product Code	Dimension	Outside roll diameter	Roll core	Adhesion
211-390	C-S-L-1-70-DA	7 x 70 cm	15.7 cm	3"	Standard
211-394	C-S-L-1-80-DA	7 x 80 cm	15.4 cm	2"	Standard
211-490	C-S-L-1-70-DA-IA	7 x 70 cm	15.7 cm	3"	Strong



#### Single labels with perforation, double self-adhesive

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core	Adhesion	Photo
211-342	C-S-L-1-60x40-SC-DA	800	58 x 35 mm	12 cm	3"	Standard	1
211-345	C-S-L-1-60x40-SU-DA (Split: bottom)	800	58 x 35 mm	10.6 cm	2"	Standard	1
211-282	C-S-L-1-60x40-SC-DA	1,000	58 x 35 mm	11 cm	1.5"	Standard	1
211-377	C-S-L-1-38x39-SC-DA	700	38 x 39 mm	10.5 cm	2"	Standard	2
211-338	C-S-L-1-70x40-SC-DA	1,000	70 x 35 mm	11 cm	1.5"	Standard	3
211-349	C-S-L-1-80x40-SC-DA	800	78 x 35 mm	12 cm	3"	Standard	3
211-449	C-S-L-1-80x40-SC-DA-IA	800	78 x 35 mm	12 cm	3"	Strong	3
211-448	C-S-L-1-80x40-SC-DA-IA	1,000	78 x 35 mm	15 cm	3"	Strong	3



**Labels 102 x 56 mm, for the Getinge documentation system**

horizontal and vertical splits, separation in 3 segments

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core	Adhesion
211-367	C-S-L-1-SL-DDOC	800	102 x 56 mm	11.6 cm	1"	Standard
211-369	C-S-L-1-SL-DDOC	800	102 x 56 mm	12 cm	1.5"	Standard
211-370	C-S-L-1-SL-DDOC	800	102 x 56 mm	13.6 cm	3"	Standard
211-469	C-S-L-1-SL-DDOC-IA	800	102 x 56 mm	12 cm	1.5"	Strong



**Single labels with perforation, removable**

The labels are made of plastic material, to be directly adhered on containers and can be removed without leaving any residues and documented.

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core
211-142	C-S-L-1-60x40-SA-R	1,000	58 x 35 mm	11 cm	3"
211-149	C-S-L-1-80x40-SA-R	1,000	78 x 35 mm	11 cm	1"

**3-line labels with indicator double self-adhesive**

for use in a GKE labelling device (see section documentation system). Each pack contains 4 or 12 rolls with 750 labels and an ink roll.

Art. No.	Product Code	Color	Qty
240-883	C-S-L-1-DA-R	red	4
240-871	C-S-L-1-DA-G	green	12
240-872	C-S-L-1-DA-B	blue	12
240-873	C-S-L-1-DA-R	red	12
240-874	C-S-L-1-DA-Y	yellow	12



**3-line ECO labels with indicator double self-adhesive**

for use in a GKE labelling device. The labels consist of a 3-layer material with standard adhesion properties. No conformity declaration and no test report available. Each pack contains 12 rolls with 750 labels, NO ink roll.

Art. No.	Product Code	Color	Qty
000-873	C-S-L-1-DA-R-ECO	red	12



**3-line labels with indicator single self-adhesive**

for use in a GKE labelling device. The labels consist of a 2 layer material and can be adhered. Each pack contains 12 rolls with 1,000 labels, NO ink roll.

Art. No.	Product Code	Color	Qty
230-872	C-S-L-1 SA-B	blue	12



### Container label for manual labelling or with printer, self-adhesive

The container labels are put into packs, pouches or slipped on containers which have to be sterilized. It can be labelled with expiry date or a 3-line documentation label can be adhered onto the container label.



Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core
211-341	C-S-L-1-CL-40x60-SA	1,000	60 x 38 mm	14 cm	3"

### Container Seal

The self-adhesive container seal seals the container and contains a process indicator. It can be manually labeled with a 3-line documentation label.

Art. No.	Product Code	Dimension	Qty
211-362	C-S-L-1-CS	70 x 29 mm 75 mm pin	1,008



### Autoclave Tape

The autoclave tape with process indicator is available on roll with 50 m length and 19 mm width and is used to seal packs.

Art. No.	Product Code	Color Change	Qty
211-351	C-S-L-1-AT-IA	green to black	12
211-352	C-S-L-1-AT-IA	green to black	48



### TYPE 2 INDICATOR SYSTEMS - BOWIE-DICK SIMULATION (BDS) TESTS

The Bowie-Dick Simulation test is a functionality test used in steam sterilizers to assess the effectiveness of air removal and steam penetration. It is typically performed daily in healthcare settings before sterilizing instruments. A failed test indicates air leaks or inadequate vacuum, requiring immediate attention to ensure sterilization reliability.

#### Compact-PCD, color: Blue

Air removal and steam penetration test. European version simulating 7 kg cotton pack according to EN ISO 11140-4 and hollow load test according to EN ISO 11140-6.

Art. No.	Product Code	Content	Qty
211-151	C-S-BDS-EUH-RCPCD	PCD, round	1
211-150	C-S-BDS-EUH-RCPCD-KIT	PCD, round, + 100 indicator strips	1+100



#### Compact-PCD, color: Purple

Air removal and steam penetration test. European Version simulating 7 kg cotton pack according to EN ISO 11140-4.

Art. No.	Product Code	Content	Qty
211-121	C-S-BDS-EU-RCPCD	PCD, round	1
211-120	C-S-BDS-EU-RCPCD-KIT	PCD, round, + 100 indicator strips	1+100



#### Compact-PCD, color: Light blue

American Bowie-Dick Simulation Test: Air removal test according to AAMI/ANSI ST79 (4 kg cotton pack) and validated with the test method described in ISO 11140-5.

Art. No.	Product Code	Content	Qty
211-131	C-S-BDS-USA-RCPCD	PCD, round	1
211-130	C-S-BDS-USA-RCPCD-KIT	PCD, round, + 100 indicator strips	1+100



#### Refill pack indicator strips for BDS-Test

for all GKE BDS-tests. A replacement seal ring is included.

Art. No.	Product Code	Content	Qty
211-111	C-S-BDS-SV1	BDS indicator strips	100
211-112	C-S-BDS-SV1	BDS indicator strips	250
211-115	C-S-BDS-SV1	BDS indicator strips	500



## TYPE 2 INDICATOR SYSTEMS - PROCESS MONITORING SYSTEMS (PMS) HOLLOW LOAD TEST SYSTEMS

PMS monitor air removal characteristics of sterilizers and are type test, eg, BD Test, Helix Test EN ISO 11140-6 or may exceed standard test challenges to ensure effective sterilization of complex load. Please consult with your representative or distributor to select the suitable test device.

### Compact-PCD, color: Green

less demanding requirements than EN ISO 11140-6

Art. No.	Product Code	Content	Qty
200-020	PM-SHL-RCPCD	PCD, round	1
211-253	C-S-PM-SHL-RCPCD-KIT	PCD, round + 100 indicator strips	1+100
200-024	PM-SHL-OCPCD	PCD, oval	1
211-254	C-S-PM-SHL-OCPCD-KIT	PCD, oval + 100 indicator strips	1+100



### Compact-PCD, color: Orange

Hollow Load Test according to EN ISO 11140-6

Art. No.	Product Code	Content	Qty
200-021	PM-HL-RCPCD	PCD, round	1
211-263	C-S-PM-HL-RCPCD-KIT	PCD, round + 100 indicator strips	1+100
200-026	PM-HL-OCPCD	PCD, oval	1
211-264	C-S-PM-HL-OCPCD-KIT	PCD, oval + 100 indicator strips	1+100



### Compact-PCD, color: Red

higher requirements than EN ISO 11140-6

Art. No.	Product Code	Content	Qty
200-029	PM-HDH-RCPCD	PCD, round	1



### Compact-PCD, color: Brown

much higher requirements than EN ISO 11140-6

Art. No.	Product Code	Content	Qty
200-030	PM-VHDH-RCPCD	PCD, round	1



## LOAD-RELATED BATCH MONITORING SYSTEMS

Test properties of Batch Monitoring Systems (BMS) are validated according to defined load configurations (Dental, Tattoo or Ophthalmologic) and monitor each batch during routine sterilization.

Art. No.	Product Code	Content	Color	Qty	Photo
200-091	BMS-Ophthal-OCPCD	PCD, oval	White	1	1
211-291	C-S-BMS-Ophthal-OCPCD-KIT	PCD, oval + 100 indicator strips	White	1+100	1
200-081	BMS-Dental-OCPCD	PCD, oval	Yellow	1	2
211-281	C-S-BMS-Dental-OCPCD-KIT	PCD, oval + 100 indicator strips	Yellow	1+100	2
200-071	BMS-Tattoo-OCPCD	PCD, oval	Black	1	3
211-271	C-S-BMS-Tattoo-OCPCD-KIT	PCD, oval + 100 indicator strips	Black	1+100	3



### REFILL PACK INDICATOR STRIPS

To be used in all GKE BMS/PMS process challenge devices. Each refill pack contains 1 seal ring for exchange in the screw cap of the PCD.

#### Standard indicator strips STEAM (121 °C, 15 min / 134 °C, 3 min)

Art. No.	Product Code	Qty
211-251	C-S-PM-SV1	100
211-252	C-S-PM-SV1	250
211-255	C-S-PM-SV1	500



#### Prion indicator strips STEAM (134 °C, 18 min)

Art. No.	Product Code	Qty
211-211	C-S-PM-SV2	100
211-212	C-S-PM-SV2	250
211-215	C-S-PM-SV2	500



## TYPE 4, 5 AND 6 INDICATORS (PACKAGE MONITORING) AS INTERNAL AND EMULATING INDICATORS FOR STEAM STERILIZATION PROCESSES

Monitor steam sterilization for solid instruments and porous goods (no hollow devices). Used in packs or unpackaged in autoclaves. Self-adhesive for documentation.

### Type 4 Indicators

SV = 121 °C, 15 min/ 132-134 °C, 3 min

Art. No.	Product Code	Dimension	Qty
211-403	C-S-P-4-SV1	65 x 14 mm	3,200



### Type 5 integrating indicators without printing possibility

SV = 121 °C, 15 min / 128 °C, 8 min / 135 °C, 3 min

Art. No.	Product Code	Dimension	Qty
211-221	C-S-P-5-SV1	14 x 65 mm	100
211-224	C-S-P-5-SV1	14 x 65 mm	400
211-226	C-S-P-5-SV1	14 x 65 mm	3,200



### Type 5 integrating indicators with printing possibility, self-adhesive

on roll with 3" core

SV = 121 °C, 15 min / 128 °C, 8 min / 135 °C, 3 min

Art. No.	Product Code	Dimension	Qty
211-230	C-S-P-5-78x48-SA-SV1	78 x 48 mm	1,000



### Type 6 Steam Package Indicator Emulating Indicator

for standard steam sterilization processes  
SV = 121 °C, 15 min / 134 °C, 3 min

Art. No.	Product Code	Dimension	Qty
211-243	C-S-P-6-SV1	23 x 66 mm	250
211-242	C-S-P-6-SV1	23 x 66 mm	500
211-241	C-S-P-6-SV1	23 x 66 mm	2,000



### Type 6 Steam Package Indicator Emulating Indicator

SV = 134 °C, 18 min (prion program)

Art. No.	Product Code	Dimension	Qty
211-241	C-S-P-6-SV2	23 x 66 mm	250
211-238	C-S-P-6-SV2	23 x 66 mm	2,000



## SELF-CONTAINED BIOLOGICAL INDICATORS

Mini-Bio-Plus self-contained biological indicator (SCBI) uses a plastic vial containing a spore disc and glass ampoule with a growth medium and pH-indicator inside. It is used for validation and routine monitoring of sterilization processes without the need to have access to a microbiological laboratory. They can also be used inside GKE process challenge devices (Bio PCDs). All SCBI fulfil the requirements according to EN ISO 11138-1+3.

### Standard SCBIs with incubation time of 24 hours

Population of 10E5 and 10E6, on paper carrier.

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Color of Cap	Population	Qty
324-501	B-S-MBP-10-5	Light blue	10E5	10
324-505	B-S-MBP-10-5	Light blue	10E5	50
324-510	B-S-MBP-10-5	Light blue	10E5	100
324-601	B-S-MBP-10-6	Dark blue	10E6	10
324-605	B-S-MBP-10-6	Dark blue	10E6	50
324-610	B-S-MBP-10-6	Dark blue	10E6	100



### Instant-SCBIs for immediate release

The 121°C and 134 °C Instant-Mini-Bio-Plus SCBI contain a type 5 chemical indicator allowing that the result of steam sterilization processes can be instantly evaluated at the end of the steam sterilization process. Therefore, it is not necessary to wait for the result of the SCBI incubation since the type 5 indicator provides equivalent or better information about the result of the sterilization process according to EN ISO 11140-1.

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Color of Cap	Population	Temp.	Qty
324-521	B-S-MBP-I-10-5-SV5	Light green	10E5	121 °C	10
324-525	B-S-MBP-I-10-5-SV5	Light green	10E5	121 °C	50
324-621	B-S-MBP-I-10-6-SV5	Dark green	10E6	121 °C	10
324-625	B-S-MBP-I-10-6-SV5	Dark green	10E6	121 °C	50
324-551	B-S-MBP-I-10-5-SV4	Light orange	10E5	134 °C	10
324-555	B-S-MBP-I-10-5-SV4	Light orange	10E5	134 °C	50
324-550	B-S-MBP-I-10-5-SV4	Light orange	10E5	134 °C	100
324-651	B-S-MBP-I-10-6-SV4	Dark orange	10E6	134 °C	10
324-655	B-S-MBP-I-10-6-SV4	Dark orange	10E6	134 °C	50
324-650	B-S-MBP-I-10-6-SV4	Dark orange	10E6	134 °C	100



### Activation Control SCBI

The SCBI with activation control contains a glass ampoule with colorless growth medium that only turns colored after activation of the SCBI, thus preventing misapplication.

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Color of Cap	Population	Qty
324-591	B-S-AC-MBP-10-5	Light blue	10E5	10
324-595	B-S-AC-MBP-10-5	Light blue	10E5	50
324-590	B-S-AC-MBP-10-5	Light blue	10E5	100
324-691	B-S-AC-MBP-10-6	Dark blue	10E6	10
324-695	B-S-AC-MBP-10-6	Dark blue	10E6	50
324-690	B-S-AC-MBP-10-6	Dark blue	10E6	100



### Activation Control 134°C Instant-SCBI

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Color of Cap	Population	Qty
324-581	B-S-AC-MBP-I-10-5 (132-137 °C)	Light orange	10E5	10
324-585	B-S-AC-MBP-I-10-5 (132-137 °C)	Light orange	10E5	50
324-580	B-S-AC-MBP-I-10-5 (132-137 °C)	Light orange	10E5	100



### Stearo-Ampoules

to monitor extreme wet steam or liquid sterilization processes. The ampoules are available in two different sizes. It contains a 1.5 or 0.2 ml *Geobacillus stearothermophilus* suspension with growth medium and pH-indicator. GKE Stearo Ampoules can be used for processes at 121 °C and 134 °C, both.

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Diameter/Height	Population [CFU/Amp.]	Qty
225-550	B-S-AMP-10-5	11 / 45 mm (1.5 ml)	10E5	50
225-650	B-S-AMP-10-6	11 / 45 mm (1.5 ml)	10E6	50
235-510	B-S-MAMP-10-5	5 / 25 mm (0.2 ml)	10E5	100
235-610	B-S-MAMP-10-6	5 / 25 mm (0.2 ml)	10E6	100



### Biological Indicator for Sterilization of liquids

Meets the requirements of ISO 11138-3 and is suitable for microbiological validation and routine control of liquid sterilization. The use of these bio-indicator ampoules is only permitted for liquid sterilizers with thermally controlled recooling.

Test organism: *Geobacillus stearothermophilus*

Art. No.	Population	Application	Qty
BI-FLDA-10	10E5	liquids	10



### SPORE STRIPS AND GROWTH MEDIA

#### Spore strips

The biological indicators (6 x 38 mm) inoculated with bacteria spores on paper carrier contain a certificate which states nominal population and D-value. All spore strips can be also used inside of process challenge devices (PCD). (See section testsets and PCDs)

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Primary package	Pop	Qty	Photo
223-501	B-S-SS-10-5	Glassine	10E5	100	1
223-505	B-S-SS-10-5	Glassine	10E5	500	1
223-510	B-S-SS-10-5	Glassine	10E5	1000	1
223-601	B-S-SS-10-6	Glassine	10E6	100	1
223-605	B-S-SS-10-6	Glassine	10E6	500	1
223-610	B-S-SS-10-6	Glassine	10E6	1000	1
BI-ST-1001-50		Paper/Foil	10E5	50	2
BI-ST-1001-100		Paper/Foil	10E5	100	2
BI-ST-1001-500		Paper/Foil	10E5	500	2
BI-ST-1001-V6-50		Paper/Foil	10E6	50	2
BI-ST-1001-V6-100		Paper/Foil	10E6	100	2
BI-ST-1001-V6-500		Paper/Foil	10E6	500	2



#### Growth media

Test tubes with aluminium screw cap (diameter: 16.1 mm) filled with TSB and pH-indicator. The test tubes have optimized dimensions and volume to fit all kind of *G. stearothermophilus* spore strips and spore discs. If germs are growing the pH-indicator changes its colour and allows a quick evaluation of the result.

Art. No.	Product Code	Process	Qty
223-010	B-S-CM	steam	10
223-100	B-S-CM	steam	100



### Spore Suspensions

In 10 ml glass bottle with a septum, suspended in 40 % ethanol/water including certificate, which states nominal population and  $D_{121^{\circ}\text{C}}$ -value for steam according to EN ISO 11138-3.



Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Population [CFU/ml]	Sterilization Process	Qty
228-107	B-S-F-SUS-10-7	10E7	Steam, Formaldehyde	10 ml
228-108	B-S-F-SUS-10-8	10E8	Steam, Formaldehyde	10 ml

### Spore Suspensions in alcoholic solution

Spore suspensions in plastic tubes, suspended in alcoholic solution. Including certificate which states nominal population.

Test organism: *Geobacillus stearothermophilus*



Art. No.	Population [CFU/ml]	Qty
SPE8204-6-5ml / -10ml	10E6	5 ml / 10 ml
SPE8205-7-5ml / -10ml	10E7	5 ml / 10 ml
SPE8206-8-5ml / -10ml	10E8	5 ml / 10 ml

### Spore Suspensions in Aqua dest.

Spore suspensions in plastic tubes, suspended in Aqua dest. including certificate which states nominal population.

Test organism: *Geobacillus stearothermophilus*



Art. No.	Population [CFU/ml]	Qty
SPW8204-6-5ml	10E6	5 ml
SPW8205-7-5ml	10E7	5 ml
SPW8206-8-5ml	10E8	5 ml

## VH202

### Indicators

#### FOR HYDROGEN PEROXIDE STERILIZATION PROCESSES

Indicators for hydrogen peroxide sterilization ensure process validation and effectiveness. They assess critical parameters like gas concentration, temperature, and exposure time, verifying that sterilization conditions meet requirements. These tools are essential for maintaining safety and compliance in sterilization procedures.



#### TYPE 1 PROCESS INDICATORS

All GKE process indicators for hydrogen peroxide sterilization processes change their color from blue to green as shown:



Endless labels to be used in printers with cutting device, double self-adhesive

Art. No.	Product Code	Dimension	Outside roll diameter	Roll core	Adhesion
214-390	C-S-V-L-1-60-DA	7 x 70 cm	14.7 cm	3"	Standard



### Single labels, perforated, double self-adhesive

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core	Adhesion	Photo
214-369	C-V-L-1-SL-DDOC	800	102 x 56 mm	12 cm	1.5"	Standard	1
214-349	C-V-L-1-80x40-SC-DA	800	78 x 35 mm	12 cm	3"	Standard	2



### 3-line labels with indicator double self-adhesive

for use in a GKE labelling device (see section documentation system). Each pack contains 2 or 12 rolls with 750 labels and an ink roll.

Art. No.	Product Code	Color	Qty
244-883	C-V-L-1-DA-R	red	2
244-873	C-V-L-1-DA-R	red	12



### Indicator Tape

50 m length, 19 mm width

Art. No.	Product Code	Color Change	Qty
214-354	C-V-L-1-AT	purple to pink	2
214-355	C-V-L-1-AT	purple to pink	10



### Process Challenge Devices (PCD) and Testset

Helix PCDs are available with different length and diameter, also available as Testset. The indicator strip is placed into the PCD. The test device is sterilized together with the load.

Art. No.	Product Code	Tube		Qty
		Diameter (mm)	Length (cm)	
200-016	PM-HPCD-TS-10	Testset with 10 PCDs		10
200-525	PM-HPCD-5-25	5	25	1
200-550	PM-HPCD-5-50	5	50	1
200-575	PM-HPCD-5-75	5	75	1
200-510	PM-HPCD-5-100	5	100	1
200-425	PM-HPCD-4-25	4	25	1
200-450	PM-HPCD-4-50	4	50	1
200-475	PM-HPCD-4-75	4	75	1
200-325	PM-HPCD-3-25	3	25	1
200-350	PM-HPCD-3-50	3	50	1
200-025	PM-HPCD-2-25	2	25	1



### Indicator strips

To be used in GKE BMS/PMS process challenge devices

Art. No.	Product Code	Qty
214-201	C-V-PM	250



### Type 4 Indicators

The indicators are placed into packages or containers to monitor the relevant variables of sterilization processes. Those indicators should only be used if solid instruments or porous goods (no hollow devices!) are sterilized. Package monitoring indicators only provide sterility information at the position inside the chamber where they are located. After sterilization they can be adhered for documentation.

The indicators are available with different stated values, different colour changes and increasing sensitivities.

Art. No.	Product Code	Color Change	Qty
214-250	C-V-P-SV6	red to yellow	160
214-251	C-V-P-SV6	red to yellow	400
214-253	C-V-P-SV6	red to yellow	3,200
214-241	C-V-P-SV7	blue to green	400
214-243	C-V-P-SV7	blue to green	3,200
214-260	C-V-P-SV8	red to orange	160
214-261	C-V-P-SV8	red to orange	400
214-221	C-V-P-SV9	blue to green	400
214-223	C-V-P-SV9	blue to green	3,200



## SELF-CONTAINED BIOLOGICAL INDICATORS

Mini-Bio-Plus self-contained biological indicator (SCBI) uses a plastic vial containing a spore plate and glass ampoule with a growth medium and pH-indicator inside. It is used for validation and routine monitoring of sterilization processes without using a microbiological laboratory. They can also be used inside GKE process challenge devices (Bio PCDs). All SCBI fulfil the requirements according to EN ISO 11138-1.

### Standard SCBIs with incubation time of 24 hours

Test organism: *Geobacillus stearothermophilus* 10E6, on different carriers.

Art. No.	Product Code	Color of Cap	Carrier	Qty
327-601	B-V-G-MBP-10-6	Light grey	Glass fiber	10
327-605	B-V-G-MBP-10-6	Light grey	Glass fiber	50
327-610	B-V-G-MBP-10-6	Light grey	Glass fiber	100
337-601	B-V-T-MBP-10-6	Colorless	Tyvek®	10
337-605	B-V-T-MBP-10-6*	Colorless	Tyvek®	50
347-601	B-V-ST-MBP-10-6	Dark grey	Stainless steel	10
347-605	B-V-ST-MBP-10-6	Dark grey	Stainless steel	50
357-601	B-V-P-MBP-10-6	Purple	PET	10
357-605	B-V-P-MBP-10-6	Purple	PET	100



### Spore Suspensions

delivered in 10 ml glass bottle with a septum, suspended in 40 % ethanol/ water and comply with EN ISO 11138-1 and are delivered with certificate which states nominal population and D-value.

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Population [CFU/ml]	Sterilization Process
229-107	B-V-SUS-10-7	10E7	Hydrogen Peroxide
229-108	B-V-SUS-10-8	10E8	Hydrogen Peroxide



### Growth media

Test tubes with aluminium screw cap (diameter: 16.1 mm) filled with TSB and pH-indicator. The test tubes have optimized dimensions and volume to fit all kind of *G. stearothermophilus* spore strips and spore discs. If germs are growing the pH-indicator changes its colour and allows a quick evaluation of the result.

Art. No.	Product Code	Process	Qty
332-010	B-V-CM	VH202	10
332-100	B-V-CM	VH202	100



### Spore strips and Spore discs

The D-values are determined by exposure of spore suspensions to hydrogen peroxide solutions. Spore suspensions analyzed in this way are used to inoculate carriers. Therefore, the influence of the carrier material on the resistance of the BI suspension remains unconsidered.

The biological indicators consist of *Geobacillus stearothermophilus* bacteria spores inoculated on different carriers with the size of 6 x 38 mm and packaged individually (in Tyvek envelope of 94 x 65 mm) or in bulk in a blister box. They also contain a certificate which states nominal population and D-value. All spore strips can be also used inside of process challenge devices (PCD).

The *Geobacillus stearothermophilus* bacteria spores are inoculated on discs with 7 mm diameter (available with different carriers) and are packaged individually (in Tyvek envelopes of 60 x 65 mm) or in bulk in a blister box.

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Carrier	Packaged	Population	Qty
332-407	B-V-ST-SS-10-4	Stainless Steel	individually	10E4	100
332-507	B-V-ST-SS-10-5	Stainless Steel	individually	10E5	100
332-607	B-V-ST-SS-10-6	Stainless Steel	individually	10E6	100
332-608	B-V-ST-SS-10-6	Stainless Steel	bulk	10E6	40
332-601	B-V-P-SS-10-6	PET	individually	10E6	100
332-604	B-V-P-SS-10-6	PET	bulk	10E6	40
332-602	B-V-G-SS-10-6	Glas fiber	individually	10E6	100
332-605	B-V-G-SS-10-6	Glas fiber	bulk	10E6	40
332-603	B-V-T-SS-10-6	Tyvek®	individually	10E6	100
332-606	B-V-T-SS-10-6	Tyvek®	bulk	10E6	40
332-417	B-V-ST-DIS-SP-10-4	Stainless Steel	individually	10E4	100
332-517	B-V-ST-DIS-SP-10-5	Stainless Steel	individually	10E5	100
332-617	B-V-ST-DIS-SP-10-6	Stainless Steel	individually	10E6	100
332-615	B-V-ST-DIS-SP-10-6	Stainless Steel	bulk	10E6	110
332-612	B-V-P-DIS-SP-10-6	PET	individually	10E6	100
332-614	B-V-P-DIS-SP-10-6	PET	bulk	10E6	110
332-616	B-V-G-DIS-SP-10-6	Glas fiber	individually	10E6	100
332-611	B-V-G-DIS-SP-10-6	Glas fiber	bulk	10E6	110
332-618	B-V-T-DIS-SP-10-6	Tyvek®	individually	10E6	100
332-613	B-V-T-DIS-SP-10-6	Tyvek®	bulk	10E6	110



# FORM

## Indicators

### FOR FORMALDEHYDE STERILIZATION PROCESSES

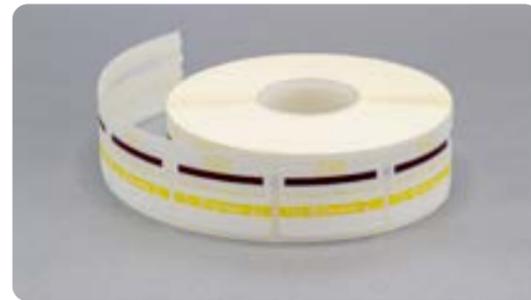
Indicators for low-temperature steam formaldehyde sterilization (LTSF) ensure process validation and effectiveness. They assess critical parameters like gas concentration, temperature, and exposure time, verifying that sterilization conditions meet required standards. These tools are essential for maintaining safety and compliance in sterilization procedures.



#### 3-line labels with indicator double self-adhesive

for use in a GKE labelling device (see section documentation system). Each pack contains 2 or 12 rolls with 750 labels and an ink roll.

Art. No.	Product Code	Color	Qty
243-884	C-F-L-1-DA-Y	yellow	2
243-874	C-F-L-1-DA-Y	yellow	12



#### Type 2 Indicator Systems Process Challenge Devices

Art. No.	Product Code	Version	Qty	Photo
200-150	PM-HPCD-2-150	helix	1	1
200-218	PM-CPCD-8	compact	1	2



#### Refill pack indicator strips

Art. No.	Product Code	Qty
213-202	C-F-PM	250



#### Type 4 Internal indicator

SV = 1,0 mol/L FO; 70 °C; 20 min

Art. No.	Product Code	Qty
213-221	C-F-P	400



## SELF-CONTAINED BIOLOGICAL INDICATORS

Mini-Bio-Plus self-contained biological indicator (SCBI) uses a plastic vial containing a spore disc and glass ampoule with a growth medium and pH-indicator inside. It is used for validation and routine monitoring of sterilization processes without the need to have access a microbiological laboratory. They can also be used inside GKE process challenge devices (Bio PCDs). All SCBI fulfil the requirements according to EN ISO 11138-1+5.

#### Standard SCBIs with incubation time of 24 hours

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Color of Cap	Population	Qty
325-601	B-F-MBP-10-6	yellow	10E6	10
325-605	B-F-MBP-10-6	yellow	10E6	50



#### Spore strips

The biological indicators (6 x 38 mm) inoculated with bacteria spores contain a certificate which states nominal population and D-value. All spore strips can be also used inside of process challenge devices (PCD).

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Primary package	Pop	Qty	Photo
223-601	B-S-SS-10-6	glassine	10E6	100	1
223-605	B-S-SS-10-6	glassine	10E6	500	1
223-610	B-S-SS-10-6	glassine	10E6	1000	1
BI-FA-4401-50		paper/foil	10E5	50	2
BI-FA-4401-100		paper/foil	10E5	100	2



#### Spore Suspensions

Delivered in 10 ml glass bottle with a septum, suspended in 40 % ethanol/water and comply with EN ISO 11138-1 and are delivered with certificate which states nominal population and D<sub>121°C</sub>-value for steam according to EN ISO 11138-3. The testing/certificate for formaldehyde has to be purchased at extra costs.

Test organism: *Geobacillus stearothermophilus*

Art. No.	Product Code	Population [CFU/ml]	Sterilization Process
228-107	B-S-F-SUS-10-7	10E7	Steam, Formaldehyde
228-108	B-S-F-SUS-10-8	10E8	Steam, Formaldehyde
228-998	Testing / Certificate of analysis		Formaldehyde



## Indicators

### FOR ETHYLENE OXIDE STERILIZATION PROCESSES

EO indicators validate sterilization by monitoring critical parameters such as gas concentration, temperature, humidity, and exposure time. They ensure compliance with standards, guaranteeing effective sterilization and safety.



#### Type 1 indicators

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core
212-349	C-E-L-1-80x40-SC-DA	800	78 x 35 mm	12 cm	3"



#### 3-line labels with indicator double self-adhesive

for use in a GKE labelling device. Each pack contains 2 or 12 rolls with 750 labels and an ink roll.

Art. No.	Product Code	Color	Qty
242-885	C-E-L-1-DA-P	purple	2
242-875	C-E-L-1-DA-P	purple	12



#### 3-line ECO labels with indicator double self-adhesive

The labels consist of a 3-layer material with standard adhesion properties. No conformity declaration and no test report available. Each pack contains 12 rolls with 750 labels, NO ink roll.

Art. No.	Product Code	Color	Qty
000-873	C-S-L-1-DA-R-ECO	red	12



#### Indicator Tape

The indicator tape with process indicator is available on roll with 50 m length and 19 mm width and is used to seal packs.

Art. No.	Product Code	Color Change	Qty
212-354	C-E-L-1-AT	red to green	10
212-355	C-E-L-1-AT	red to green	50



#### Indicator strips

for use as a type 2 indicator test system in the GKE stainless steel Helix-PCD according to Line/Pickerill for type testing according to EN 1422 or with GKE process challenge device or test sets, see chapter Test sets and PCDs

Art. No.	Product Code	Color Change	Qty	Photo
212-202	C-E-PM	blue to green	250	1
200-028	C-E-PM-HPCD		1	2



#### Type 4 + 5 indicators

SV = 600 mg/L EO, 54 °C, 20 min, RH > 30 % (Type 4)

SV = 600 mg/L EO, 54 °C, 35 min, RH = 60 % (Type 5)

Art. No.	Product Code	Type	Color Change	Qty
212-360	C-E-P-4-SV3	type 4	blue to green	3,200
212-224	C-E-P-5	type 5	yellow to blue	400
212-226	C-E-P-5	type 5	yellow to blue	3,200



## SELF-CONTAINED BIOLOGICAL INDICATORS

Mini-Bio-Plus self-contained biological indicator (SCBI) uses a plastic vial containing a spore disc and glass ampoule with a growth medium and pH-indicator inside. It is used for validation and routine monitoring of sterilization processes without the need to have access a microbiological laboratory. They can also be used inside GKE process challenge devices (Bio PCDs). All SCBI fulfil the requirements according to EN ISO 11138-1+2.

### Standard SCBIs with incubation time of 48 hours

Test organism: *Bacillus atrophaeus*

Art. No.	Product Code	Color of Cap	Population	Qty
326-605	B-E-MBP-10-6	red	10E6	50
326-610	B-E-MBP-10-6	red	10E6	100



### Spore strips

on paper carrier, according to EN ISO 11138-2.

Test organism: *Bacillus atrophaeus*

Art. No.	Product Code	Primary package	Population	Qty
221-601	B-E-H-SS-10-6	glassine	10E6	100
221-605	B-E-H-SS-10-6	glassine	10E6	500
221-610	B-E-H-SS-10-6	glassine	10E6	1000
BI-EO-3101-50		paper/foil	10E6	50
BI-EO-3101-100		paper/foil	10E6	100
BI-EO-3101-500		paper/foil	10E6	500



### Growth media

Test tubes with aluminium screw cap (diameter: 16.1 mm) filled with TSB and pH-indicator. The test tubes have optimized dimensions and volume to fit all kind of *B. atrophaeus* spore strips and spore discs. If germs are growing the pH-indicator changes its colour and allows a quick evaluation of the result.

Art. No.	Product Code	Process	Qty
221-010	B-E-H-CM	ethylene oxide, dry heat	10
221-100	B-E-H-CM	ethylene oxide, dry heat	100



## Spore Suspensions

delivered with certificate which states nominal population and D-value for ethylene oxide EN ISO 11138-2 EP and USP.

Test organism: *Bacillus atrophaeus*

Art. No.	Product Code	Population [CFU/ml]	Qty
226-107	B-E-H-SUS-10-7	10E7	10 ml
226-108	B-E-H-SUS-10-8	10E8	10 ml
226-109	B-E-H-SUS-10-9	10E9	10 ml



### Spore Suspension in alcoholic solution

Spore suspension in plastic tubes, suspended in 80% ethanol/water. Includes certificate with nominal population.

Test organism: *Bacillus atrophaeus*

Art. No.	Population [CFU/ml]	Qty
SPE8101-7-5-5ml/-10 ml	10E7	5 ml / 10 ml
SPE8102-8-5-5ml/-10 ml	10E8	5 ml / 10 ml
SPE8103-9-5-5ml/-10 ml	10E9	5 ml / 10 ml



### Spore Suspension in Aqua dest

Spore suspension in plastic tubes, suspended in distilled water. Includes certificate with nominal population.

Test organism: *Bacillus atrophaeus*

Art. No.	Population [CFU/ml]	Qty
SPW8101-7-5-5ml	10E7	5 ml
SPW8102-8-5-5ml	10E8	5 ml
SPW8103-9-5-5ml	10E9	5 ml



**DRY**

## Indicators

### FOR DRY HEAT STERILIZATION PROCESSES

Indicators for dry heat sterilization ensure process validation by monitoring critical parameters like temperature and exposure time. They verify the effectiveness of sterilization cycles, ensuring safety and compliance with required standards.



#### Spore strips

Biological indicator according to ISO 11138-4, packaged in glassine envelopes.

Test organism: *Bacillus atrophaeus*

Art. No.	Product Code	Primary packaging	Population	Qty
221-601	B-E-H-SS-10-6	glassine	10E6	100
221-605	B-E-H-SS-10-6	glassine	10E6	500
221-610	B-E-H-SS-10-6	glassine	10E6	1000



#### Spore strips

Biological indicator according to ISO 11138-4, packaged in medical paper.

Test organism: *Bacillus atrophaeus*

Art. No.	Primary packaging	Population	Qty
BI-HL-2001-50	paper/foil	10E6	50
BI-HL-2001-100	paper/foil	10E6	100
BI-HL-2001-250	paper/foil	10E6	250



#### Growth media

Test tubes with aluminium screw cap (diameter: 16.1 mm) filled with TSB and pH-indicator. The test tubes have optimized dimensions and volume to fit all kind of *B. atrophaeus* spore strips and spore discs. If germs are growing the pH-indicator changes its colour and allows a quick evaluation of the result.

Art. No.	Product Code	Process	Qty
221-010	B-E-H-CM	ethylene oxide, dry heat	10
221-100	B-E-H-CM	ethylene oxide, dry heat	100



#### Spore Suspensions

The suspension is delivered with certificate which states nominal population and D-value for ethylene oxide EN ISO 11138-2 EP and USP. The certificate for dry heat is available at an extra cost

Test organism: *Bacillus atrophaeus*

Art. No.	Product Code	Population [CFU/ml]	Qty
226-107	B-E-H-SUS-10-7	10E7	10 ml
226-108	B-E-H-SUS-10-8	10E8	10 ml
226-109	B-E-H-SUS-10-9	10E9	10 ml
226-999	Certificate of analysis/Testing		Dry heat



## Testsets and PCDs

### FOR STERILIZATION PROCESS MONITORING

Process challenge devices provide information about the penetration of sterilant into hollow objects. Test sets with various PCDs, each having different penetration challenges, make it possible to evaluate the penetration performance of a process. These tools help maintain compliance with standards and ensure safety in critical applications.



### TESTSETS AND PCDS

Testsets are used to test the penetration limits of the sterilant in different sterilization processes. The testsets contain PCDs with different penetration characteristics. Please order the corresponding biological or chemical indicator strips, a PCD or testset, see (steam), (ethylene oxide), (formaldehyde) or (hydrogen peroxide/plasma).

#### Compact PCD Test Set

To test steam, ethylene oxide and formaldehyde sterilization processes.

Art. No.	Product Code	Content	Qty
200-211	PM-RCPCD-1	200-071 (Tattoo)	1
200-212	PM-RCPCD-2		1
200-213	PM-RCPCD-3	200-081 (Dental)	1
200-214	PM-RCPCD-4		1
200-215	PM-RCPCD-5		1
200-216	PM-RCPCD-6	200-091 (Ophthal)	1
200-217	PM-RCPCD-7	200-020 (green)	1
200-218	PM-RCPCD-8	200-021 (orange)	1
200-219	PM-RCPCD-9	200-029 (red)	1
200-220	PM-RCPCD-10	200-030 (brown)	1
200-210	PM-RCPCD-TS	Testset with 10 CPCDs	10



#### Helix-Test Set

To test steam and formaldehyde sterilization processes.

Two different Test Sets are available to test:  
small sterilizers (200-013), see table 1.  
large sterilizers (200-017), see table 2.

All PCD included in the Test Sets are available individually.

Art. No.	Product Code	Tube		Qty
		Diameter (mm)	Length (cm)	
200-025	PM-HPCD-2-25	2	25	1
200-050	PM-HPCD-2-50	2	50	1
200-075	PM-HPCD-2-75	2	75	1
200-100	PM-HPCD-2-100	2	100	1
200-150	PM-HPCD-2-150	2	150	1
200-013	PM-HPCD-TS-5	Testset with above PCD		5

Art. No.	Product Code	Tube		Qty
		Diameter (mm)	Length (cm)	
200-150	PM-HPCD-2-150	2	150	1
200-302	PM-HPCD-2-300	2	300	1
200-452	PM-HPCD-2-450	2	450	1
200-153	PM-HPCD-3-150	3	150	1
200-303	PM-HPCD-3-300	3	300	1
200-154	PM-HPCD-4-150	4	150	1
200-304	PM-HPCD-4-300	4	300	1
200-510	PM-HPCD-5-100	5	100	1
200-205	PM-HPCD-5-200	5	200	1
200-305	PM-HPCD-5-300	5	300	1
200-405	PM-HPCD-5-400	5	400	1
200-505	PM-HPCD-5-500	5	500	1
200-605	PM-HPCD-5-600	5	600	1
200-017	PM-HPCD-TS-13	Testset with above PCD		13



## BIO PCDs Process Challenge Devices (PCD) for self-contained biological indicators

Bio PCD, color: green, to be used with all Mini-Bio-Plus SCBIs described before, for validation and routine monitoring of steam, ethylene oxide, formaldehyde and hydrogen peroxide sterilization processes or Helix-PCD according to EN 1422:2009 for ethylene oxide sterilization processes.

It is recommended to use the round versions in large and the oval versions in small sterilizers.

Art. No.	Product Code	PCD Version	Penetration Characteristics
300-031	B-PM-OCPCD-0	oval	Very low requirements for air removal
300-032	B-PM-RCPCD-0	round	
300-033	B-PM-OCPCD-1	oval	Minimal requirements for air removal
300-034	B-PM-RCPCD-1	round	
300-035	B-PM-OCPCD-2	oval	Low requirements for air removal
300-036	B-PM-RCPCD-2	round	
300-037	B-PM-OCPCD-3	oval	Air removal less difficult than Hollow Load Test according to EN ISO 11140-6
300-038	B-PM-RCPCD-3	round	
300-039	B-PM-OCPCD-4	oval	Air removal equal to Hollow Load Test according to EN ISO 11140-6
300-040	B-PM-RCPCD-4	round	
300-041	B-PM-RCPCD-5	round	Air removal more difficult than Hollow Load Test according to EN ISO 11140-6
300-041	B-PM-RCPCD-6	round	
300-028	B-E-PM-HPCD	Metal Helix	Type test according to Line/Pickerill (EN 1422:2009 EO)



## Replacement parts for PCDs

Art. No.	Product Code	Qty
300-005	Replacement screw cap (M14x1 thread)	5
300-006	Replacement seal kit for all PCDs listed above	5



## Crusher

to activate all GKE SCBIs. The GKE incubator includes a crusher.

Art. No.	Product Code	Material	Qty
224-002	I-C	Stainless steel	1
224-004	I-PC	Plastic	10



## Documentation System

The documentation system, consisting of a hand labeling device and labels, ensures efficient and reliable patient record management. It enables precise labeling of instruments and materials, supporting traceability and compliance with documentation standards in healthcare settings.



## HAND LABELLING DEVICES

The GKE documentation system is used for batch- and patient-related traceability after sterilization of medical devices.

By using a GKE labelling device a label of the same content including production and expiry date, batch number and responsible person is adhered on each pack and on the documentation sheet. After opening the sterile pack in the operation room the label can be removed from the package and adhered into the patient file. Thus all information provided on each pack can be traced back from the patient to the processing and approval.

The labels are available in different colours, optionally with or without indicator.

## Labeling Device

Art. No.	Product Code	1. Printing line	2. + 3. Printing line
240-820	D-G-NL	3 alpha-numeric and 9 numeric digits	12 numeric digits
240-830	D-G-AL	12 alpha-numeric digits	
240-892	Ink roll	for all GKE hand labelling devices	



Labels with indicator can be found in the sections on steam, hydrogen peroxide, formaldehyde and ethylene oxide.

## 3-line labels without indicator, double self-adhesive

for use in a GKE labelling gun. Each pack contains 4 or 12 rolls of 750 labels and an ink roll.

Art. No.	Product Code	Color	Qty
240-853	D-G-DA-R	red	4
240-861	D-G-DA-G	green	12
240-862	D-G-DA-B	blue	12
240-863	D-G-DA-R	red	12
240-864	D-G-DA-Y	yellow	12



**3-line ECO labels without indicator, double self-adhesive**

The labels consist of a 3-layer material with standard adhesion properties. No conformity declaration and no test report available. Each pack contains 12 rolls with 750 labels, NO ink roll.

Art. No.	Product Code	Color	Qty
000-863	D-L-DA-R-ECO	red	12



**3-line labels without indicator, single self-adhesive**

The labels consist of a 2 layer material and can be adhered. Each pack contains 12 rolls with 1,000 labels, NO ink roll.

Art. No.	Product Code	Color	Qty
230-864	D-L-SA-Y	yellow	12



**SEAL TESTS**

**Seal Test for routine control of sealing seams**

For rotary sealing machines (173 x 76,2 mm)

Art. No.	Product Code	Process	Qty
200-311	SEAL-TEST	Seal indicator to check paper/ plastic film pouches	100
200-312	SEAL-TEST		250
200-321	HDPE-SEAL-TEST	Seal indicator to check Tyvek® pouches	100



**Seal Test for routine control of sealing seams**

for bar sealing machines (250 x 76.2 mm)

Art. No.	Product Code	Process	Qty
200-331	BAR-SEAL-TEST	Seal indicator to check paper/ plastic film pouches	100



## INCUBATOR AND ACCESSORIES

The incubator is available in four versions with different temperatures. The incubation temperature is visible in the display. All incubators are either available with an aluminium block to incubate SCBIs or alternatively without aluminium block. In this case an aluminium block available for different applications has to be ordered separately. The plug contains a CE conformity for the low voltage directive.

### Dry Bath Incubators with aluminium block

for 12 SCBIs (hole diameter 10 mm)

Art. No.	Product Code	Temperature	Application
610-119	I-37-AB-MBP	37	to incubate <i>B. atrophaeus</i> biological indicators
610-120	I-57-AB-MBP	57	to incubate <i>G. stearotherophilus</i> biological indicators
610-121	I-V-AB-MBP	30-60	variable temperature selection
610-122	I-V-T-AB-MBP	30-60	variable temperature selection and programming of the incubation time



### Dry Bath Incubators without aluminium block

Art. No.	Product Code	Temperature	Application
610-109	I-37	37	to incubate <i>B. atrophaeus</i> biological indicators
610-110	I-57	57	to incubate <i>G. stearotherophilus</i> biological indicators
610-111	I-V	30-60	variable temperature selection
610-112	I-V-T	30-60	variable temperature selection and programming of the incubation time



### Aluminium blocks

to insert SCBIs, Stearo-Ampoules or growth medium tubes (12 pcs each).

Art. No.	Product Code	Diameter	Application
610-113	I-AB-MBP	10 mm	for all GKE Mini-Bio-Plus SCBIs
610-114	I-AB-AMP	11 mm	for all GKE Mini and Stearo-Ampoules
610-115	I-AB-CM	16.5 mm	for all GKE growth medium tubes



### Adapter set for Belimed / BHT-WD

for washer disinfectors with pressure box. Adapter set for PCD for flexible endoscopes PM-RIBI-2 for use in Belimed- and BHT-WD.

Art. No.	Qty
PM-RIBI-DK	1



### Adapter for Olympus washer disinfectors

for PCD for flexible endoscopes. PM-RIBI-2 for use in Olympus-WD.

Art. No.	Qty
PM-RIBI-OLY	1



### Adapter for Belimed washer disinfectors with CMS (Channel Monitoring System)

Adapter for PCD for flexible endoscopes PM-RIBI-2 for use in Belimed-WD with channel monitoring system.

Art. No.	Qty
PM-RIBI-BEL-PP	1



### Fixing aid for TD / CTD

Fixing aid for fastening biological indicators TD and CTD in washer disinfectors.

Art. No.	Qty
SH-21201-5	5



### Fixing aid for biological indicators

Fixing aid for fastening biological indicators in washer disinfectors. Available in long and short version.

Art. No.	Length	Qty
KB-21411	short	100
KB-21421	long (BWA-GSA-FS-OPS-RAM-RAMS)	100



### Protective pouches for safe return of indicators

Art. No.	Content	Qty
TY-21501	watertight Tyvek-pouches	100
PE-21601	pressure lock pouches	100



### Spare parts for GKE PCDs (BDS-Test and Batch Monitoring)

Art. No.	Content	Qty	Photo
211-117	Teflon indicator holder (BDS-Test)	5	1
200-113	Replacement screw cap (with M10x1 thread)	5	2
200-111	Replacement screw cap (with M12x1 thread)	5	3
200-102	Teflon indicator holder (Batch Monitoring)	5	4
200-108	Seal ring for M12x1 thread	1	5



## Abbreviations

BI .....	Biological Indicator
BMS.....	Batch Monitoring System
CFU .....	Colony Forming Unit
CI .....	Chemical Indicator
CPI.....	Cleaning Process Monitoring Indicator
EP.....	European Pharmacopeia
LTSF .....	Low-Temperature-Steam-Formaldehyde
MIS instruments .....	minimal invasive surgical instruments
MOQ .....	Minimum Order Quantity
PCD .....	Process Challenge Device
PMS.....	Process Monitoring System
POP .....	Population
PP.....	Polypropylene
RI .....	Cleaning Indicator (Reinigungsindikator)
SCBI .....	Self-Contained Biological Indicator
SV.....	Stated Value
TSB .....	Tryptic Soy Broth
USP .....	United States Pharmacopeia
WD .....	Washer Disinfector

