

Gündem Inc. ABGIndicators[®] and Other Biological Indicators & Accessories

Product Catalog



Sport Strips Ampoules, Suspensions, Self-Contained Mini-Bio-Plus Indicators

for the control of steam, formaldehyde, hydrogen peroxide, ethylene oxide and dry heat sterilization processes

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General information about biological indicators

The quality of sterilization procedures in hospitals has reached high standards. The necessary control procedures are expensive, but they ensure long-term germ-free surgical operations in all areas.

International and local standards and the European Medical Device Directive (MDD) require validation, cluster control and documentation of sterilization processes.

As in industry, hospitals have to validate, cluster control and document their processes. Validation and control of sterilization processes is performed by chemical and/or biological parametric tests. Validation using biological indicators is necessary in the following cases:

- not applicable in places where sensors cannot be physically placed, such as in the structure of the products to be sterilized (for example: small holes, crevices, sealed areas, and oil-coated areas)
- The lumens of hollow instruments are so narrow that the temperature difference between the Non-Condensable Gases (NGs) (inside) and the vapor (outside) cannot be detected. Gases in such small lumens reach the vapor-temperature-level several 100 µl times faster.
- The presence of condensation (vapor to water) cannot be detected by physical means (for example: if the temperature rise is too slow, the KEGs inside the capsule will have time to heat up and will not show a detectable temperature difference.
- the surface structure of medical devices requires special testing (for example: porous rubber stoppers).
- salt is present in the sterilant and in the packages and/or containers to be sterilized. The salt dissolves as a film during condensation and causes a major change in the resistance characteristics.
- moisture contains substances that change the pH-value (e.g. corrosion-inhibitors) or materials of medical instruments (e.g. aluminum surfaces) can react with water to produce elemental hydroxides.

In the above cases all surfaces or liquids should be inoculated with biological suspension indicators. After a valid population determination, reduced process cycles should be run to obtain a survival curve to define the kinetics of mortality on/inside these critical surfaces. Process Revitalization Devices (PCDs) designed for porous and hollow loads and biological indicators can be used to monitor the condition inside such critical interior areas.

Biological indicators are defined in the European and International standards EN ISO 11138- parts 1 and 5. Specific reference biological microbes have been selected for many and widely used sterilization methods, e.g. *Geobacillus stearothermophilus* for steam, formaldehyde and hydrogen peroxide, *Bacillus atrophaeus for ethylene oxide and dry heat and Bacillus pumilus for irradiation.*

Depending on the type of sterilization process, a specific resistance characteristic of biological indicators is required to prove the success of the defined sterilization process. In such a sterilization cycle the spore population always decreases in a state of exponential mortality characteristic (so called "first order reaction kinetics"). However, the population will never reach the true 0-value. Therefore, the modern definition of "sterile" products does not state that there is no biological activity, but that there is a certain probability of so-called Sterility Safety Level (SAL).

According to European Standard EN 556, the Strerility Safety Level must be either at least ¹⁰⁻⁶ CFU per piece or lower. This means that out of 1 million units, growth can only be seen in 1 unit.

During the sterilization process, both the kinetics of death and penetration characteristics should be checked together.

The total resistance of a biological indicator depends on the resistance of each microbe and the population of microbes. The resistance of each microbe is defined by the decimal decrease value, which is the time required to

reduce the population of a biological indicator by one tenth of its original population. The total durability of the biological indicator is expressed by the value F_{BIO} .

F_{BIO} = **D**_{121°C} value x log (population)

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Example	Population	D ₁₂₁ value	F _{Bio} value
	[CFU/unit]	[dak]	[dak]
1	10 ⁶	1,5	9
2	10 ⁵	2	10

This is illustrated by two examples shown in the table below

As seen above, the D-value of a given strain never changes, but its growth depends on the processing conditions. Therefore, the certificate of each batch of biological indicators must indicate the population of the product, the resistance of each biological indicator and the total resistance.

gke, Steri-Record[®] recommends biological indicators in accordance with the EN ISO 11138 series. The certificates on all packages contain all the necessary information mentioned above. Each package also contains instructions for use. More information is available in our brochure.

The sterilized biological indicators are still in the glasin envelope. Together with the envelope containing these spore strips, an unused but labeled spore strip should be sent to the microbiology laboratory. All strips should be aseptically transferred to Tryptic Soybean liquid medium (TSB) and grown for at least 7 days. If the spore type is in doubt, a 1ml solution of TS agar plate (TSA) can be used to determine the spore type. TSA bottles without spore strips should not show any growth, but untreated spore strips should grow. Treated spore strips should be identified individually (see gke - technical information). *gke* recommends culture medium test tubes with a pH indicator for quick evaluation.

Self-Feeding-Based Biological Indicators (SBBIs) also contain culture media in a separate vial for direct cultivation by the user. They should not be used for dry heat or formaldehyde sterilization. For more details, please refer to our brochure "Self-Growing Biological Indicators (SBIs)".

Process Characterization Devices (PCDs) are used to represent the "bad-case" penetration characteristics of the load. PCDs as defined in EN 867-5 "Hollow Load Test" and DIN 58921 can be used. Biological indicators in the PCD check the penetration of the sterilant.

1. gke Steri-Record® Self-Feeding Biological Indicators (SBI)

Mini-Bio-Plus self-biological indicators (SIBIs) consist of a spore plate in a plastic bottle and a glass bottle containing a growth medium with a pH indicator.

They are used for validation and routine control of many sterilization processes without the need for a laboratory. In order to better differentiate between the versions of the ENTBIs, there are different cover colors for all of them. They can also be used inside *gke* Process Revitalization Devices (Bio-C-PCDs), see clause 1.5. All ENBBIs conform to EN ISO 11138-1 and fully meet all requirements.

1.1. For steam sterilization according to EN ISO 11138-3

STEAM

G. Stearothermophilus exists in populations 10^5 and 10^6 , in the paper carrier. There are two versions, Standard and Instant:

Code-No.	Product code	Cover color	Population	Amount
	Standard version	(incubation tim	e 24 hours)	
235-324-501				10
235-324-505	B-S-MBP-10-5	Light blue	10 ⁵	50
235-324-510		-		100
235-324-601				10
235-324-605	B-S-MBP-10-6	Dark blue	10 ⁶	50
235-324-610				100

1. Standard version Incubation time 24 hours

2. Instant release For instant release

The Instant-Mini-Bio-Plus Self-Feeding Biological Indicator (SBBI) contains a Class 5 chemical indicator that allows immediate evaluation of the result of the sterilization process at the end of the steam sterilization process at 132-137°C. Therefore, the Class 5 indicator provides equivalent or better information without the need to wait for the incubation results of the KBBI in accordance with EN ISO 11140-1

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Code-No.	Product code	Cover color	Population	Amount
	Instant versio	n for instant rel	ease	
235-324-551				10
235-324-555	D-3-IVIDM-I-10-3-3V4	Light orange	10 ⁵	50
235-324-550				100
235-324-651				10
235-324-655	D-3-IVIDM-I-10-0-3V4	Dark orange	10 ⁶	50
235-324-650	IIIStallt-IVIDP-30DI	- 5-		100

1.2. For formaldehyde (LTSF*) sterilization according to EN ISO 11138-5

G. stearothermophilus is present in 10⁶ populations, in the paper carrier.

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The culture medium contains a pH indicator as well as a neutralizing agent for residual formaldehyde gas. This eliminates the need for treatment with Sodium Sulfate as described in EN ISO 11138-5.

* LTSF: Low Temperature Steam Formaldehyde.



Code-No.	Product Code	Cover color	Population	Amount
235-325-601		Vallow	106	10
235-325-605	D-F-IVIDP-10-0	TEIIOW	10°	50

1.3. For the entire hydrogen peroxide / plasma sterilization process *G. stearothermophilus*, present in 10⁶ populations, does not contain a paper carrier.





Code-No.	Product Code	Cover color	Population	Amount
235-327-601		\M/bito	106	10
235-327-605	D-V-IVIF D-10-0	vvnite	10°	50

1.4. For ethylene oxide sterilization according to EN ISO 11138-2 *B. atrophaeus* is present in 10⁶ populations, in the paper carrier.

EO

EO Mini-8 B. atra LOT 55412	EO Mini-8 B. atm LOT 55412		Mi	EO	1
B. atm LOT 55412	B. atm	-	-		Ľ
LOT 55412	55412	1	B. 8		
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-	-				
	-				
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Code-No.	Product Code	Cover color	Population	Amount
235-326-605		Pod	106	50
235-326-610		Reu	106	100

1.5. Process Revitalization Devices (PCD). For self-feeding medium biological indicators (SBBIs)

Bio-C-PCDs, color: green, are used for validation and routine control of steam, ethylene oxide, formaldehyde and hydrogen peroxide sterilization methods for all Mini-Bio-Plus CSCs described above.

Round ones are recommended for large sterilizers and oval ones for small sterilizers. A PCD containing an ENBBI is referred to as a Class 2 indicator in the EN ISO 11140-1 standard.

Each PCD contains 10 gaskets as a replacement for the gasket inside the cover.



Code-No.	Product code	PCD version	Penetration Characteristics
235-300-011	B-PM-OCPCD-1	oval	Minimal requirement for air
235-300-016	B-PM-RCPCD-1	round	venting
235-300-012	B-PM-OCPCD-2	oval	Low requirement for air evacu-
235-300-017	B-PM-RCPCD-2	round	ation
235-300-013	B-PM-OCPCD-3	oval	Air venting Hollow Load Test at
235-300-018	B-PM-RCPCD-3	round	(Draft EN ISO 11140-6)
235-300-014	B-PM-OCPCD-4	oval	Air venting Hollow Load Test of
235-300-019	B-PM-RCPCD-4		(Draft EN ISO 11140-6)
235-300-015	B-PM-RCPCD-5	round	Air venting Hollow Load Test with greater difficulty than EN 867-5 (Draft EN ISO 11140-6)

1.6 Accessories

1.6.1 Exchange parts for PCDs



1.6.2 For Crusher Self-Feeding-mediated Biological Indicators (SBBI)

All **gke** incubators already contain a crusher.

gke Amponie Crusher	Code-No.	Product code	Amount
	235-224-002	I-C	1



2. gke Steri-Record[®] Stearo-Ampuller G. stearothermophilus

STEAM

in accordance with EN ISO 11138-1+3 with suspension and culture media

for extremely wet steam or liquid sterilization processes. The ampoule *contains* 1.5 ml of *Geob. Stearother*mophilus suspension and culture medium with pH indicator and has populations of 10⁵ and 10.⁶



Code-No.	Product code	Population	Amount	
235-225-550	B-S-AMP-10-5	105	50	
235-225-650	B-S-AMP-10-6	10 ⁶	50	

3. gke Steri-Record[®] Incubators and accessories

3.1. Incubators and related aluminum blocks

Incubators are available in four different versions and with different temperatures. The incubation temperature can be seen on the display. Different aluminum block versions should be selected for different applications.

The devices comply with CE for the low voltage directive.



Code-No.	Product code	Content	Temperature [°C]
235-610-119	I-37	Incubator	37
235-610-120	I-57	At constant temperature	57
235-610-121	I-V-AB-MBP	Temperature-selectable incubator	
235-610-122	I-V-T-AB-MBP	Incubator with adjustable tempera- ture selection and programmable incubation time	30-60
235-610-113	I-AB-MBP	Aluminum block for all gke KBBIs, with crusher for crushing KBBIs	
235-610-114	I-AB-AMP	All gke Sterao Ampoules + test tubes with culture media Aluminum block for ENTILs	-

4. gke Steri-Record® Suspensions and cultivation kit

Spore suspensions (10ml) are available in 40% ethanol/water in a glass bottle with a rubber septum cap and conform to EN ISO 11138-1.

4.1. For steam, formaldehyde and hydrogen peroxide sterilization processes *Geob. Stearothermophilus (ATCC No. 7953)*

The suspension conforms to EN ISO 11138-3 for vapor and is delivered with a certificate of analysis specifying the population and D_{121° C-value.

G. stearothermophilus is also used for formaldehyde and hydrogen peroxide sterilization processes. A standard for H O₂₂ is not yet in place. *D-value determination for* formaldehyde and **VH2O2** hydrogen peroxide* can be defined for an extra charge.



Code-No.	Product code	Population	Population in each bottle
235-228-107	B-S-F-V-SUS-10-7	10 ⁷	10 ⁸
235-228-108	B-S-F-V-SUS-10-8	10 ⁸	10 ⁹

* D-value determination is performed separately for each process parameter.

4.2. For dry heat and ethylene oxide sterilization processes *B. atrophaeus (ATCC No. 9372)*



STEAM

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VH2O2

STEAM

FORM

The suspension complies with EN ISO 11138-2+4 for ethylene oxide and dry heat and is delivered with a certificate of analysis indicating the population and D_{121°} C-value.



Code-No.	Product code	Population	Each bottle Population
235-226-107	B-E-H-SUS-10-7	10 ⁷	10 ⁸
235-226-108	B-E-H-SUS-10-8	10 ⁸	10 ⁹
235-226-109	B-E-H-SUS-10-9	10 ⁹	10 ¹⁰

4.3. Direct Seeding Kit. Geob. with Stearothermophilus suspension

for the testing of complex instruments in steam, formaldehyde or hydrogen peroxide sterilization processes.

The precision injector can also be used for ethylene oxide and dry heat sterilization if a *B. atrophaeus* suspension is purchased.

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Code-No.	Product code	Content
235-228-110	Sowing Kit	in 40% ethanol/water 2 x 1.5 ml <i>Geob. stearothermophilus</i> 10 ⁷ CFU/ml suspension, 20cm long needle with a precision syringe.

5. ABGIndicators ® Strip Biological Indicators

Strip bioindicators contain bacterial spores planted on a 6 x 38 mm filter paper placed in a glasin envelope. These strips are available in packs of 100, 500 and 1000 pieces. Each pack contains certificates with population and D-value.

All strips can also be used in process revitalization devices (PCDs). The envelopes of the spore strips can be opened in an aseptic environment and placed in the PCD (just like gke-strips-chemical indicators). At the end of the sterilization cycle, the PCD should not be opened and should be sent to the microbiology laboratory where they should be removed from the PCD and incubated in an aseptic environment. Please refer to the gke -Chemical Catalog for more information.

5.1 For steam and formaldehyde sterilization processes

Geob. stearothermophilus (ATCC No. 7953)

Both resistance values for code 234-223-601 are defined in accordance with EN ISO 11138-3+5 as specified in certificate D_{FA} and $D_{121^{\circ}C}$.

Code-No.	Product code	Sterilization process	Population	Amount
234-223-501				100
234-223-505	Steam-S-10-5		10 ⁵	500
234-223-510		Cteam		1.000
234-223-601		Steam		100
234-223-602	Steam-S10-6		10 ⁶	200
234-223-610				1.000

5.2 Hydrogen peroxide for sterilization processes

Geob. stearothermophilus (ATCC No. 7953)

The spore strips are in a PET plastic carrier. The definition of resistance is not yet in the standards. D-values are defined on a resistometer and indicated on the certificate.

A B C Indicators Spore strip	Code-No.	Product code	Population	Amount
Order#: 234-223-602	234-332-601	V-Steam-S-10-6	106	100
LOT/EXP.: 202309/2025-09-17				

for hydrogen peroxide/plasma

ABGIndi Spore strip # 234-223-602 202309/2025-09-17

234-332-601	V-Steam-S-10-6	10 ⁶	100

5.3 For ethylene oxide and dry heat sterilization processes B. atrophaeus (ATCC-No. 9372) in accordance with EN ISO 11138-2+4.

DRY EO

		Code-No.	Product code	Population	Amount
ABEI		234-221-501	B-E-H-SS-10-5	10 ^₅	100
Spore strip	E L	234-221-601			100
Order#: 234-221-601 Bacillus Atrophaeus (ATCC 9372)	HIN Y	234-221-605	B-E-H-SS-10-6	10 ⁶	500
LOT/EXP.: 2023xx/2025-xx-xx		234-221-610			1.000

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VH2O2

STEAM

FORM

6. Culture medium. In test tube.

Tryptic Soybean medium (TSB) with pH indicator in a plastic screw-top test bottle. The size and volume of the test tube are optimized to fit all spore strips. If microbes grow, the pH indicator changes its color, allowing a quick evaluation of the result.

6.1 For steam and hydrogen peroxide sterilization processes

STEAM
VH2O2

G. stearothermophilus

Code-No.	Product code	Amount
235-223-010	DCVCM	10
235-223-100	D-2-V-CIVI	100

6.2 For formaldehyde sterilization processes

The medium contains a neutralizing agent for formaldehyde remaining after sterilization so that it does not need to be treated with $Na_2 SO_3$ as defined in EN ISO 11138-5.

G. stearothermophilus

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Code-No.	Product code	Amount
235-330-010	B-F-CM	10
235-330-100		100

6.3 For ethylene oxide and dry heat sterilization processes

DRY	
EO	

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B. atrophaeus

Code-No.	Product code	Amount
235-221-010	B-E-H-CM	10
235-221-100		100

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