Test Report

Equivalence tests of class 2 indicators with the references Standard Bowie-Dick Test Package according to EN 285 and „Hollow Load“PCD according to EN 867-5

Client:	gke GmbH Auf der Lind 10 65529 Waldems Esch Germany
Date of receipt:	2008-02-18
Test report no.:	082068
Date of release:	2008-03-20
Number of pages:	24 pages

Glashütten, 2008-03-20

Dipl.-Ing. D. Kaiser
Director of Chemical Laboratory

Philipp Kloos
Assistance Chemical Laboratory

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☎ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

Content

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☎ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

1 Introduction of the SAL test laboratory

SAL GmbH, hereafter named “SAL”, is accredited from ZLG (German.: Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten; English: Central Authority for health protection of the states with regard to medicinal products and medical devices) as a test laboratory according to the directives 93/42/EWG, 90/385/EWG and EN ISO/IEC 17025 to carry out microbiological hygienic and physical tests:

- Equipment qualification and process validation for
  - Cleaning
  - Disinfection (chemical and thermal)
  - Packaging
  - Sterilization (with steam, dry heat, ethylene oxide, formaldehyde and H_2O_2)
- Sterilization monitoring material, for example
  - Biological indicators
  - Chemical indicators
  - PCD systems (Bowie-Dick-Tests, batch monitoring systems, simulation tests)
- Medical devices

Copies of the accreditation certificate and the accreditation scope are in the annex.

2 Job definition and background information

The customer, gke-GmbH, Waldems, Germany, hereafter named „gke“, is a manufacturer of indicators according to ISO 11140-1 to monitor steam sterilization processes. gke has provided a class 2 indicator test device and asked SAL to prove equivalence with the Bowie-Dick (BD) test and the hollow load test.

The first equivalents test is carried out with the BD test package of 7 kg according to EN 285 as a reference. For the second equivalents test the standard PCD “Hollow Load” according to EN 867-5 is used as a reference. The used test materials are described in detail in chapter 3.

According EN ISO 11140-1 a class 2 indicator consists of a specific test load, which is called Process Challenge Device (PCD) in the standard, together with a compatible indicator strip, which is called indicator system in the standard. Only both components together form a test system which is called “indicator” in the standard EN ISO 11140-1, as it is used in practice.

The standard BD 7 kg test package according to EN 285 is not used anymore in healthcare routine monitoring. The effort to prepare a standard test package is fairly high. Furthermore the characteristics of this test depend on the quality of the cotton towels, the package density, etc. so that the test characteristics cannot be

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

reproducibly assured in routine monitoring. Therefore the test standard EN ISO 11140-4 has been developed to prove equivalence of a BD simulation test. The design of such a BD simulation test is not specified. However the test procedure according to EN ISO 11140-4 assures that it has the same or even higher air removal sensitivity in a steam sterilization process than the reference standard BD test 7 kg cotton pack.

In the standard EN 867-5 a hollow process challenge device (PCD) is described among others which is made from PTFE and is called “Hollow Load”. However this PCD is not suitable for daily use because of its material characteristics and is in practice only used as a reference model. The standard allows the use of other designs and other materials. An alternative test system, suitable for daily use, must have the same or a higher sensitivity in air removal and steam penetration than the reference “Hollow Load” PCD described in the standard together with used indicator system which must have same the indicator characteristics like the used reference biological indicator. Furthermore the alternative test device needs to pass the described leak test according to EN 867-5.

The tested indicator is used as a type test for steam sterilizers according to EN 285 and EN 13060 type B. This type test is performed in an empty sterilizer chamber after an operation intermission of the sterilizer to assure an acceptable operation of the sterilizer before the sterilization of goods is continued.

The manufacturer standard for large sterilizers EN 285 was amended at the beginning of 2008. In the past there was only the standard Bowie-Dick test defined as a type test for those sterilizers. In the new version of 2008 the compulsory amendment A1 defines the test PCD “Hollow Load” according to EN 867-5 as a second type test (EN 285:2006 + A1:2008).

For that reason the requested test procedure at SAL should prove, that the class 2 indicators provided by gke, meet the requirements of both sterilizer type tests according to EN 285:2008.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

3 Used test material

3.1 gke indicators

The following indicators have been provided by gke to conduct the tests:

Art. no.:	211-150
Batch no.:	160105
Name:	Chemo-D-BDS-1-C-H-EU
Description:	Starter kit with Compact-PCD, colour: blue, BD-Simulation according EN ISO 11140-4 and hollow load test according EN 867-5 „Hollow Load“ and 100 self-adhesive indicator strips. This starter kit is equivalent to the combination of both articles Art. no. 211-151, Chemo-D-BDS-PCD-C-H-EU Replacement-PCD and Art. no. 211-110/ -112/ -115, Chemo-D-BDS-1/ -2,5/ -5 Indicator strips

The gke PCD consists of an outside plastic case with a stainless steel tube inside which is connected with a stainless steel capsule at the end to contain the indicator strip. The capsule is closed at the end with a stainless steel screw cap with a viton sealing. When the screw cap is unscrewed, the indicator strip can be placed in a PTFE holder. After closing the cap the indicator strip is located at the closed end of the hollow capsule volume which is the most difficult location of the PCD for steam penetration.
The indicator strips have six indicator bars which can show a graduated air removal performance (see *Table 1*).

Table 1 Colour change of the indicator strip

	untreated
	no steam penetration
	insufficient steam penetration
	sufficient steam penetration

The PCD has additionally a stainless steel hook to hang the PCD on a sterilization trolley during sterilization.

The gke PCDs are used with an indicator system (indicator strip). The indicator substrate changes colour (see table 1) during the influence of the necessary temperature-time-frame in presence of water from yellow to black.

Since the PCD can be positioned horizontally or vertically in the sterilizer chamber the tests have to be carried out in both positions.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

Figure 1 Test system: gke Compact-PCD blue.

Table 2 *Dimensions of the tested gke Compact-PCD.*

PCD	Plastic case	Tube diameter	Capsule	Tube length	Space between tube end and plastic case
Compact-PCD, round	Round slightly conical, 10 cm long , 3,2 cm inside diameter Colour: blue	2 mm	7 mm	100 cm	0 cm

3.2 References

The equivalence tests are carried out against two reference test devices, the standard cotton test package according to EN 285 and the “Hollow Load” PCD according to EN 867-5.

3.2.1 Standard test package according to EN 285

The standard test package according to ISO 11140-4 is equivalent to the standard test package according to EN 285. The test package is composed of plain cotton sheets, each bleached to white and having approximate dimensions of 900 mm x 1200 mm. The number of threads per centimeter in the warp is 30 ± 6 and the number of threads in the weft 27 ± 5. The areic mass is 185 ± 5 g/cm². The edges which are not selvedges are not hemmed.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

The sheets were not subjected to any fabric conditioning agent during laundering and have a relative humidity of 40 % to 60 % and a temperature between 20 °C to 30 °C before they are folded and used.

After equilibration the sheets are folded to approximately 220 mm x 300 mm and stacked to a height of 250 mm after compression by hand. The pack is wrapped in a similar fabric and secured with tape not exceeding 25 mm in width. Afterwards the package is weighted. The total mass of the pack is 7,0 kg ± 2 %.

Before usage, the pack is exposed to four consecutive cycles using the B2 test cycle according to ISO 11140-4. After processing, the pack is aired in an environment between 20 °C and 30 °C and relative humidity of between 40 % to 60 %.

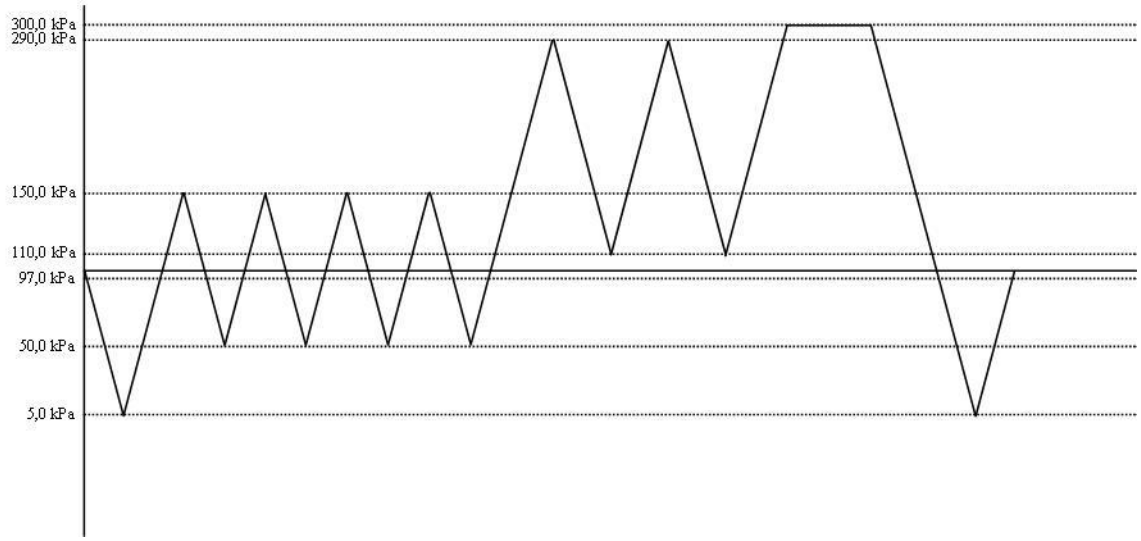


Figure 2 B2 test cycle according to ISO 11140-4.

After airing and prior to use, it is measured using a suitable calibrated temperature and humidity probe if the temperature and humidity of the pack are between 20 °C to 30 °C and 40 % to 60 % relative humidity.

The reference fault conditions have to meet the following criteria according to ISO 11140-4:

- The elapsed time between the chamber attaining the set operating pressure and the chamber reference temperature attaining the set temperature shall not exceed 5s.
- At the time the chamber reference temperature attains the set temperature, the temperature measured in the standard test pack shall show a temperature depression of 2 K or greater.
- The temperature depression shall remain at 2 K or greater throughout the reference fault period.
- The test equilibration time shall be 90 s.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

- The temperature depression at the beginning of the reference fault period shall be not greater than 7 K.
- The temperature depression at the end of the reference fault period shall be not greater than 4 K.
- The temperature depression at the end of the minimum permitted equilibration time shall be not greater than 2 K.
- The temperature depression at the end of the exposure time, or 10 min, whichever is shorter, shall not be greater than 1 K.
- The reference integrated fault (RIF) determined as the area bounded by the trace of the chamber reference temperature and the temperature at the centre of the standard test pack shall be between 120 s x K for a cycle at 134 °C for 3,5 min, and 120 s x K and 1080 s x K for a cycle at 121 °C for 15 min.

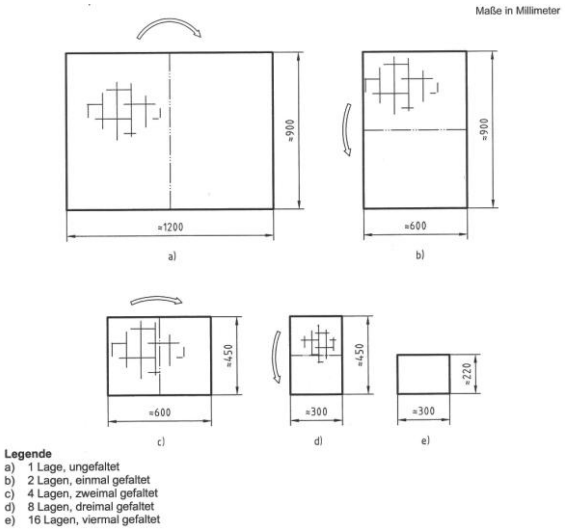


Figure 3 Folding and assembling the test pack.

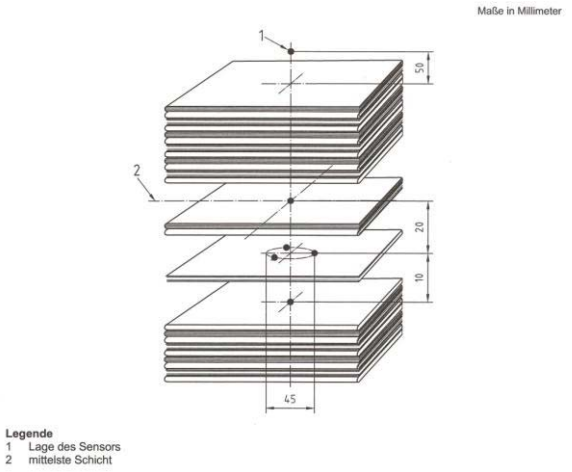


Figure 4 Location of temperature sensors within the test pack.

3.2.2 Reference PCD „Hollow Load“

The European standard EN 867-5 contains the description of a helix PCD „Hollow Load“ (see figure 2). The PCD consists of a capsule for placing the indicator strip in which is connected with a lumen of the same inner dimensions in its whole length. The capsule is cylindrical with the same cross-section over its whole length. Furthermore the PCD complies with the following specifications according EN 867-5:

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 🖃 info@sal-gmbh.com

Wall thickness:	0,5 mm ± 0,025 mm
Inner diameter:	2 mm ± 0,1 mm
Length:	1500 mm ± 15 mm
Capsule volume:	10 g ± 1 g
Free capsule volume: and the capsule volume	6% ± 1 % of the difference between the full inner volume
Material:	Polytetrafluoroethylene (PTFE)

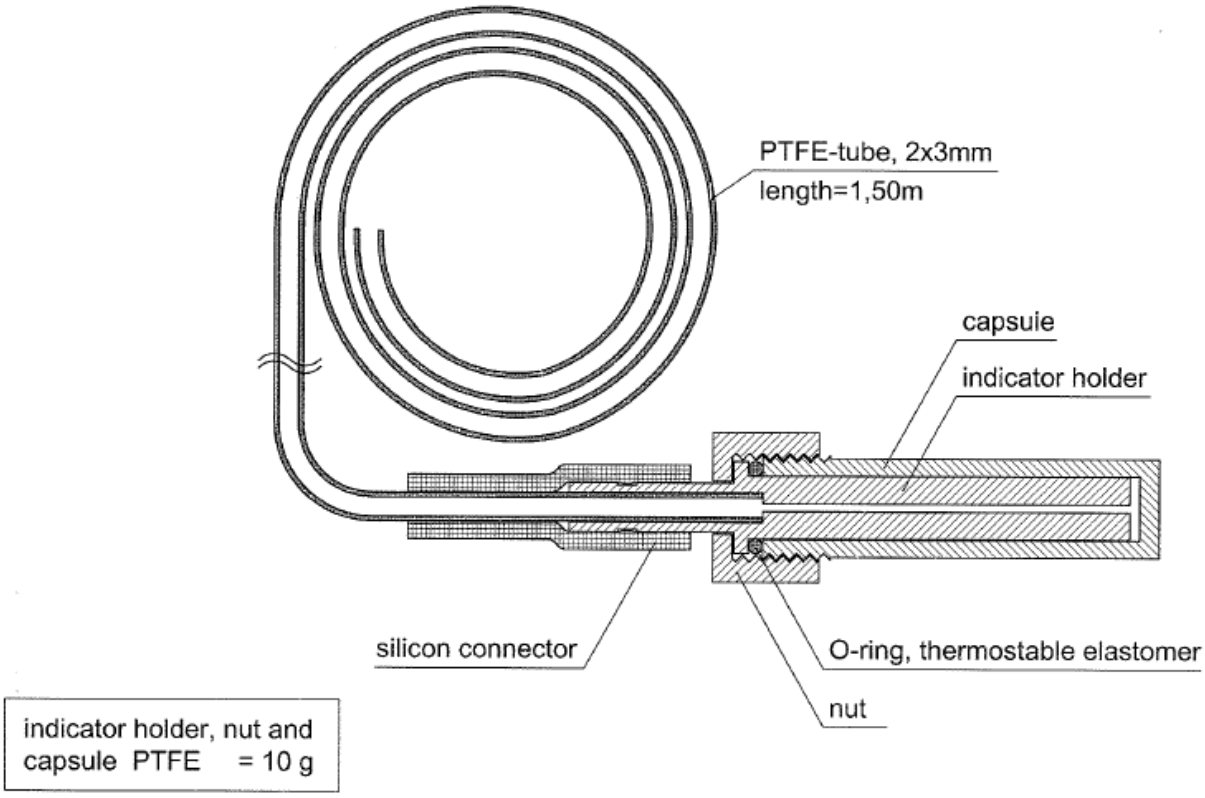


Figure 5 Helix-PCD „Hollow Load“ according EN 867-5.

3.3 Used test material

3.3.1 Steam test sterilizer

The test sterilizer (Lautenschläger, type 3119) used meets the requirements of the standards EN 285 and ISO 11140-4 (see annex 2). To avoid condensation on the walls and the chamber door, the chamber is encased by a heated double jacket and also the door is heated. Between door and chamber there is a pneumatic sealing which is charged with steam to eliminate a potential leakage risk. With the controlling software all basic parameters (i.e. pressure gradients and pressure changing points) are selectable. The chamber volume is 318 liter.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

To secure the reproducibility of the sterilization programs the feeding water for steam generation is pretreated with a complex feeding water conditioning (see Figure 6).

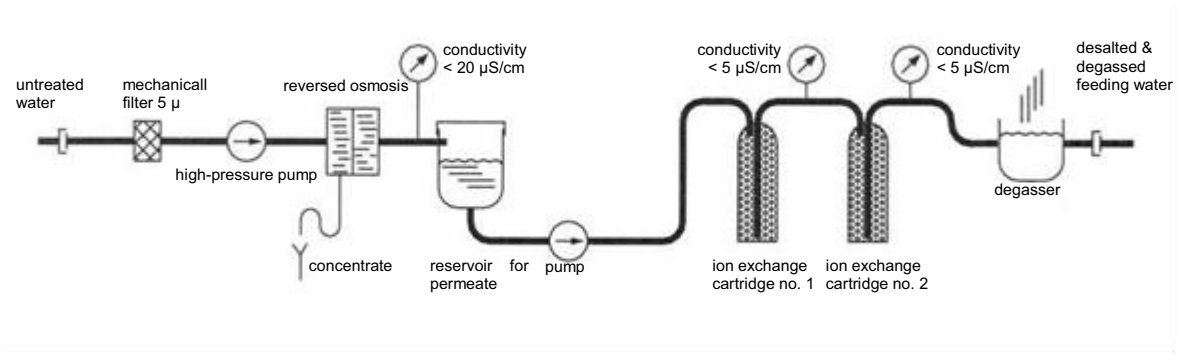


Figure 6 Feeding water conditioning.

The untreated tap water (drinking water of the public pipeline) is filtered with a 5 µ particle filter to protect the downstream sensitive reversed osmosis (RO) from coarse dirt. The reversed osmosis membrane consists of a polysulphone / polyamide foil and is formed like a helix. The salt retention of approx. 96% reduces the conductivity of the untreated water to 2 - 4 µS/cm. However the membrane is transparent to all gases like air and CO_2 dissolved in water. The remaining conductivity is mostly caused by dissolved CO_2 which is in balance with carbonic acid. Therefore the permeat typically has a pH of 5,5 - 6. A high-pressure pump of approx. 14 bar before the membrane presses the water through the RO membrane into a permeate reservoir. To further reduce the conductivity of the permeate, it is passing an ion exchanger afterwards. For safety reasons a second ion exchange cartridge is connected in series and behind each cartridge the conductivity is measured. The boiler feeding water should not exeed a conductivity of 5 µS/cm. The remaining gas dissolved in the permeate is removed in a downstream degasser by heating up to 95°C before the steam generator is fed.

3.3.2 Dry heat oven

The dry heat oven, type ULP 500 from Memmert has a power of 2 kW and a chamber volume of 108 liters. The dry heat oven is heated electrically. The working temperature ranges from 30 °C to 300 °C. The temperature in the chamber is continuously controlled with a microprocessor controller which is working with pulse package controlling. The controller has a permanent power adaption. The temperature is measured with a PT100 4-wire-test device. The setting accuracy is ± 1°C. The air circulation is carried out through an adjustable internal blower.

3.3.3 Climatic chamber

The climatic chamber, type KBF 720 from Binder GmbH has a power of 2,95 kW and a chamber volume of 700 liters. It is equipped with a multifunctional microprocessor

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

screen controller with 2-channel technology for temperature and humidity and a digital display accurate to one-tenth of a degree resp. 0.1 % r.H.
The chamber controls humidity and temperature. The temperature range is from +10 °C to +90 °C with a variation of less than 1 °C. The humidity range is from 10 % to 90 % r.H. with a variation of 1.5 %.

3.3.4 Thermocouples and multi channel writer

NiCr-Ni thermocouples type K with a diameter of 0.5 mm are used. For thermometric recording the multi channel writer M4250 from Eurotherm Chessel is used meeting the requirements of the standard EN ISO 11140-4.

3.3.5 Microbiological laboratory

SAL operates a microbiological laboratory with security level 2 which is licensed by the state government of Hesse (see attachment 8) and supervised by a graduated technical biologist. The laboratory holds the following equipment:

- Clean bench type CA/REV 4 from Clean Air for sterile working. The clean bench is annually serviced and tested.
- Phase contrast microscope type BX 40 from Olympus for optical characterization of microorganisms.
- Sterilizers to produce sterile growth media.
- Incubators with permanent online monitoring of the set temperature. When exceeding the critical temperature band, the device provides a fault message
- Bioreactor for growing bacterial cultures
- Centrifuge for separation of bacterial cultures.

3.3.6 Biological indicators

Biological indicators from gke-GmbH in form of spore strips are used. The used strain is the standard test germ for steam sterilization processes (Geobacillus stearothermophilus ATCC 7953) according ISO 11138-3 (certificate see annex 5).

Ref. no.: 3167362
D_{121}-value: 1,6 min.
Population: $2,0 \times 10^6$
z-value: 9,7°C
F-$Bio_{121°C}$: 10,1 min

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

3.3.7 Sterility test of biological indicators

Used material for sterility test:

- CASO-bouillon according to EP and USP, 9 ml in a test tube, manufacturer Heipha GmbH, order no. 308 r.
- Untreated biological indicator of the tested batch.

Experimental procedure according to the internal test procedure PA 6.1-01-04 “vitally test of biological indicators”:

Within the clean bench the biological indicators which were exposed to the sterilization process are taken aseptically out of their packaging and put into a test tube with growth media. As a check an untreated biological indicator is put into a test tube with growth media and incubated. Also a test tube without indicator is incubated.

The test tubes are incubated at 57 °C for 7 days. The clouding of the growth media shows the production of biomass and the vitality of the biological indicator. The check with the untreated biological indicator has to show growth and the test tube without indicator must not show vitality. If the exposed biological indicators show no growth than the tested sterilization process was successful.

4 Test procedures according EN ISO 11140-4

4.1 Determination of indicator strength during and after steam sterilization

4.1.1 Sterilization stability

4.1.1.1 Test procedure
The indicator is exposed to three consecutive test cycles of both B1 and B2 cycles according to ISO 11140-4 at 134 °C (see Figure 7 and Figure 2). The pressure gradient during evacuation and the drying phase amounts at least 400 kPa/ min. The indicator is taken out of the sterilization chamber after sterilization and visually inspected.

4.1.1.2 Assessment criteria
The indicator must not show any visual damages after the test cycles.

4.1.1.3 Test results
The indicator shows no visual damages like loosen or leaking of seals after the three B1 and the three B2 test cycles.
The test has been repeated three times with the same result.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

4.1.2 Drop test

4.1.2.1 Test procedure
The indicator is lifted to a height of 1000 mm and held in this position. The height shall not deviate more than 2 % of the set height. The height is the distance between the indicator's lowest point and the impact surface before dropping.

The indicator is dropped from two starting positions:
a) vertically with the screw cab downwards
b) horizontally with the flat area downwards

After the drop, the indicator is visually checked for damages.

4.1.2.2 Assessment criteria
The indicator shall not be damaged through the drop test. Damage occurring during the drop test which can be demonstrated as not impairing the interpretation of the indicator in normal use nor, for re-usable test loads, the subsequent re-use of the test load shall not constitute a failure.

4.1.2.3 Test results
The indicator was neither damaged from the vertical drop nor from the horizontal drop.
The test has been repeated three times with the same result.

4.2 Indicator system format

4.2.1 Test procedure
It is checked how many percent of the area of the indicator strip are covered with indicator reagent by determination of the respective area. Furthermore the distance between the indicator areas are determined, the color of the paper surveyed and the difference between the relative reflectance density of the endpoint color of the indicator and the paper color is determined.

4.2.2 Assessment criteria
At least 30 % of the paper strip area shall be covered with indicator reagent.
The distance between two nearby indicator areas shall be less than or equal to 20 mm.
The color of the indicator strip has to be sensed uniform.
The difference between the relative reflectance density between of the endpoint color of the indicator and the paper color shall be at least 0.3.

4.2.3 Test results
The indicator reagent covers 56 % of the carrier part which is documented after sterilization. The other part which is removed before documentation and not needed for interpretation of the indicator result was not considered for this calculation.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

The pattern of the indicator reagent on the carrier allows an easy interpretation of the color change. The indicator areas are printed in such a manner that they are arranged along the indicator capsule. For this reason the color change of each area does not occur at the same time but subsequent. Therefore the air removal performance can be shown graduated.

The endpoint color of the indicator is black and differs visually very clearly from the white paper carrier. For this reason the determination of the relative reflectance density was not carried out.

4.3 Performance requirements for the indicator system

4.3.1 Bleeding test

4.3.1.1 Test procedure

One layer of paper which is also used as the indicator carrier is brought in close contact with the indicator reagent. In this case, the indicator strip is so designed that it is folded before use and the indicator reagent is covered by its own carrier. The indicator sterilized according to the manufacturer's specifications. Before and after the treatment in the sterilization chamber the indicator, the paper cover and the paper carrier are visually checked if the requirements are met.

4.3.1.2 Assessment criteria

During sterilization the indicator reagent shall not bleed on or penetrate through the paper cover.

4.3.1.3 Test results

The indicator reagent does not bleed on or penetrate through the paper cover.
The test has been repeated three times with the same result.

4.3.2 Indicator system color change test in dry heat

4.3.2.1 Test procedure

The test is carried out in the above described dry heat oven which allows to maintain a temperature ± 2°K at a set temperature between 117,5°C and 140°C.
During testing a relative humidity in the oven of below 5 % has been assured.
The indicator system (indicator strip) is put in the oven which is preheated up to 140°C. After 30 minutes the indicator system is taken out of the oven.

4.3.2.2 Assessment criteria

The indicator strip shall show no discernible color change after exposure to dry heat at 140 °C for not less than 30 min. With some indicators the indicator strips may show a slight color change after exposure to dry heat; this shall be acceptable if the change that occurs is slight or markedly different from that brought about by exposure to steam within the limits specified by the manufacturer.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 🖃 info@sal-gmbh.com

4.3.2.3 Test results

The indicator strip shows a slight brownish color change after exposure to the dry heat process. However this color change is markedly different from the endpoint color after a steam sterilization process.
The test has been repeated three times with the same result.

4.3.3 Accelerated ageing of the indicator system

4.3.3.1 Test procedure

The indicator strip is put into a tempered climatic chamber at 65 °C and 80 % relative humidity for 7 days.

4.3.3.2 Assessment criteria

After accelerated ageing the paper shall have a color which is uniform to visual observation.
If any change in the indicator occurs during ageing, it shall be different from the change on exposure to saturated steam and shall either inactivate the indicator system so that no further change can take place or not affect the performance of the indicator system.

4.3.3.3 Test results

After accelerated ageing the paper has a color which is uniform to visual observation.
The color of the indicator strip becomes a little darker. However the performance of the indicator system is not affected.
The test has been repeated three times with the same result.

4.4 Performance requirements for the process challenge device (PCD)

The test cycles B2 (air removal by trans-atmospheric pulsing) and B3 (air removal by super-atmospheric pulsing) according to ISO 11140-4 are not able to remove the air out of the tested process challenge device (PCD). That is the reason why the tests with those two cycles are not performed. Only the tests with the B1 (air removal by sub-atmospheric pulsing) test cycle is carried out.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

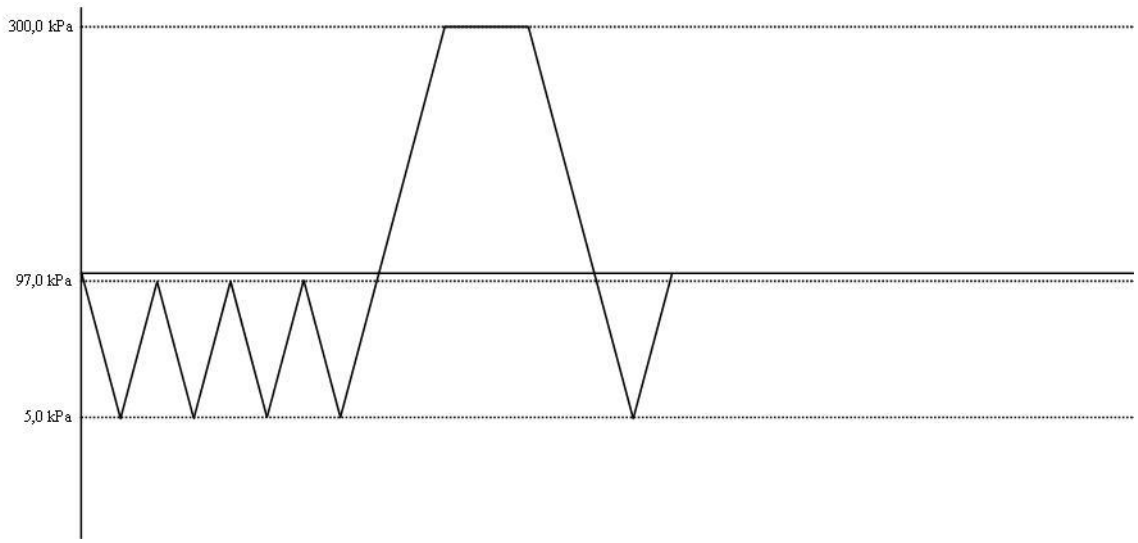


Figure 7 B1 test cycle according to ISO 11140-4.

4.4.1 Tests with the B1 PASS cycle

4.4.1.1 Test procedure

The B1 test cycle according to ISO 11140-4 (see Figure 7) with a sterilization temperature of 121 °C with 15 min, 132 °C, 134 °C and 137 °C with 3,5 min sterilization time is used. All pressure gradients are set to 45.0 kPa/ min.
In contrast to the standard the customer quotes that the tested indicator can be used with longer sterilization times (121 °C up to 30 min and 134 °C up to 9 min) without losing remarkable senility. That is the reason why the tests are also carried out with these sterilization times.

4.4.1.2 Assessment criteria

The indicator shall reach a color which is uniform to visual observation after each sterilization process.

4.4.1.3 Test result

The indicator changes color from yellow to black after each sterilization process and reaches a color which is uniform to visual observation

4.4.2 Test with the B1 FAIL cycle – modified air removal stage

4.4.2.1 Test procedure

The lower pressure changing point of the B1 test cycle is raised in 1.0 kPa steps until the tested indicator does not reach its complete endpoint.

4.4.2.2 Assessment criteria

The tested indicator shall show a FAIL earlier or at the same time as the reference standard Bowie-Dick test pack and not reach its complete endpoint.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

4.4.2.3 Test result

The tested indicator shows an incomplete color change at a lower pressure changing point of 14 kPa. The reference standard test pack shows a FAIL at a lower pressure changing point of 16 kPa. Thus the tested indicator is more sensitive to an insufficient air removal than the standard cotton test pack.

4.4.3 Test with the B1 FAIL cycle – induced leak

4.4.3.1 Test procedure

During the B1 PASS cycle a defined leak is induced. The amount of air which flows into the chamber is increased until the tested indicator shows a FAIL and does not reach its complete endpoint.

4.4.3.2 Assessment criteria

The tested indicator shall show a FAIL earlier or at the same time as the reference standard Bowie-Dick test pack and not reach its complete endpoint.

4.4.3.3 Test result

The tested indicator shows an incomplete color change at an air amount of 10 l/ h. The reference standard test pack shows a FAIL at an air amount of 20 l/ h. Thus the tested indicator is more sensitive to induced air than the standard cotton test pack.

4.4.4 Test with the B1 FAIL cycle – air injection

4.4.4.1 Test procedure

During the last steam injection of the B1 PASS cycle air is injected at a pressure of 97 kPa. The amount of injected air is increased until the tested indicator shows a FAIL and does not reach its complete endpoint.

4.4.4.2 Assessment criteria

The tested indicator shall show a FAIL earlier or at the same time as the reference standard Bowie-Dick test pack and not reach its complete endpoint.

4.4.4.3 Test result

The tested indicator shows an incomplete color change at an air injection of 150 ml. The reference standard test pack shows a FAIL at the same amount of air injection. Thus the tested indicator is as sensitive to induced air as the standard cotton test pack.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 🖃 info@sal-gmbh.com

5 Test procedure and test methods according to EN 867-5

5.1 Compatibility of the gke PCD materials

In the gke-PCDs the following materials are used:
- PVDF Polyvinyldiflouride – outside case, blue
- PPSU Polyphenylsulphone – grip surface of the screw cap
- PTFE Polytetrafluoroethylene - Teflon pin to hold the indicator strip
- Stainless steel – coiled tube and indicator capsule inside
- Viton-sealing

The characteristics of the used materials are well-known, so it is not necessary to carry out the compatibility tests of the materials. A risk analysis is made (see paragraph 5.1.1 – 5.1.6).

5.1.1 Extractable substances

The indicator strip only gets in contact with the materials PTFE (Teflon pin) and stainless steel. Both materials and also the other materials used in the PCD are known not to release extractable substances in steam sterilization processes. A change of the water pH caused by extractable substances of the materials during contact with water is excluded.

5.1.2 Water absorption

The used materials do not absorb water.

5.1.3 Stability

The used materials cannot absorb water, a change of the dimensions by water absorption is excluded. The thermal expansion characteristics of the used materials at the temperatures they are exposed to during sterilization processes are known and uncritical.

5.1.4 Effect of the aqueous extract on the indicator system (indicator strip)

No substances of the materials used in the gke PCDs are extracted, so an effect on the indicator system is excluded.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📨 info@sal-gmbh.com

5.1.5 Effect of water absorption of the PCD material on the indicator system (indicator strip)

The materials used in the ***gke*** PCDs do not absorb water. An effect on the indicator system is excluded.

5.1.6 Effect on biological indicators

According to the state of the art it is well-known that both used materials do not have negative effects on the growth of biological indicators or the colour change characteristics of chemical indicators. Therefore the corresponding test described in EN 867-5 has not been carried out.

5.1.7 Sealing of the cap (sealing test)

5.1.7.1 Test procedure
The inner lumen of the gke PCD is taken out and put under pressure with an air filled syringe and an adapter while the closed cap of the PCD is put in a water bath and observed.
This test is repeated in an oil bath heated up to 140 °C which is the maximum temperature in which the PCD may be used in steam sterilization processes.

5.1.7.2 Assessment criteria
No air shall leak out of the PCD.

5.1.7.3 Test result
The cap is observed, during both tests no bubbles are visible, the cap seals the inner lumen of the PCD.

5.2 Performance of the indicator

5.2.1 - Test of the indicator system with dry heat

This test is already covered in chapter 4.3.2.

5.2.2 - Test of the indicator with dry heat

5.2.2.1 Test procedure
The test is carried out with the same dry heat oven as the test before.

The indicator system and the gke PCDs are dried at a temperature of 110°C until the weight is constant. The dried gke PCD is placed in the dry heat oven with the cap not screwed until 140°C are reached. The indicator system is quickly put into the gke

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 🖃 info@sal-gmbh.com

PCD, the cap is screwed and both are exposed to the temperature of 140°C for 40 minutes.

5.2.2.2 Assessment criteria
The indicator system shall show no color change to the color endpoint.

5.2.2.3 Test result
The gke indicator system showed the colour yellow, a color change to the color endpoint black has not occurred.
The test has been repeated three times with the same result.

5.2.3 Test with dry, saturated steam

The tests are carried out with a test sterilizer according EN 285 and ISO 11140-4 (see annex 2).

The test cycles are carried out with different parameters for air removal, as described in the following diagrams and explanations.
Passed test results (color change to black has occurred) are described as “PASS result” and failed test results (no color change to black has occurred) are described as “FAIL results”).

5.2.3.1 Test under „PASS-conditions“

5.2.3.1.1 Test procedure
For the test under “PASS conditions” the following test cycle according EN 867-5 is used:

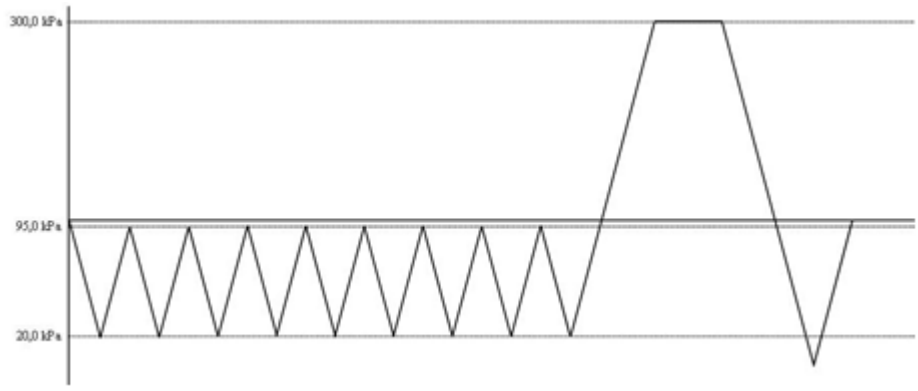


Figure 8 Sterilization cycle with a fractionated vacuum under „PASS conditions“.

Fractionated vacuum:	9 x 20,0 kPa – 95,0 kPa
Sterilization temperature:	132 °C, 134 °C or 137 °C
Sterilization time:	3,5 min
Pressure gradients:	45,0 kPa/ min

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 🖃 info@sal-gmbh.com

5.2.3.1.2 Assessment criteria
The indicator shall show a „PASS result“, that means the indicator strip placed in the gke PCD shall completely change color to the color endpoint black.

5.2.3.1.3 Test result
In all of the above described PCD assemblies the gke indicator system shows a complete color change to the color endpoint black. The test cycle with fractionated vacuum air removal was able to penetrate the BMS with steam. The indicator showed a “PASS result”.
The test has been repeated three times with the same result.

5.2.3.2 Test under “FAIL conditions”

5.2.3.2.1 Test procedure
A chemical indicator system designed for the gke PCD is placed into the gke PCD and an inoculated carrier as described above is put in the reference helix PCD “Hollow Load” before treatment. For the test cycle under „FAIL conditions“ the test cycle for “PASS conditions” used in the test before is changed by raising the lower pressure changing point according EN 867-5, annex D, in steps of 1,0 kPa.
This is continued until the gke indicator and the reference helix PCD “Hollow Load” according EN 867-5 show a “FAIL result”. Therefore a gke indicator and a reference helix PCD is put in the test cycle at the same time.

5.2.3.2.2 Assessment criteria
The tested indicator shall not show a „FAIL result“ later than the reference helix PCD „Hollow Load“ according EN 867-5.

5.2.3.2.3 Test result
The tested indicator shows the first „FAIL result“ at a lower pressure changing point of 29 kPa. The reference helix PCD “Hollow Load” according EN 867-5 shows the first “FAIL result” at a lower pressure changing point of 46 kPa (see test documentation annex 1). The tested indicator is more sensitive to insufficient air removal than the reference helix PCD according EN 867-5.
The used biological indicators in the reference PCD “Hollow Load” were analyzed in our microbiological laboratory according to the standard ISO 11138. No growth complies with a “PASS result” and growth complies with a “FAIL result”.
The test has been repeated three times with the same result.

5.3 Test with biological indicators

5.3.1 Test procedure
The above described inoculated carriers (biological indicator strips) are placed both in the three gke BMS test assemblies described above and in the reference helix PCD “Hollow Load”. These test systems are treated in the following test cycles:

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

a) Test cycle according EN 867-5, annex D (see test under “PASS conditions“)
b) Test cycle according EN 867-5, annex D (see test under “PASS conditions“) with a sterilization time of 1,5 min. instead of 3,5 min.

5.3.2 Assessment criteria

In the test cycle a) the biological indicators placed in the PCDs shall not show any growth.
In test cycle b) at least one of the inoculated carriers shall show growth in less than 50% of the sterilization time.

5.3.3 Test result

In test cycle a) the biological indicators placed in the PCDs do not show any growth.
In test cycle b) all inoculated germs show growth in less than 50% of the sterilization time.
The tests have been repeated three times with the same result.

6 Summary of the test results

The above mentioned Bowie-Dick-Simulation-Test is an indicator of class 2 according to EN ISO 11140-1 and fulfills all requirements for a Bowie-Dick cotton pack described in EN 285. Equivalence is tested with the B1 reference cycle according to EN ISO 11140-4. The test device cannot be tested in the test cycles B2 and B3 since those cycles are unable to remove the air from that test system. As a result the test device exceeds the requirements for air removal and steam penetration according to the standard reference Bowie-Dick cotton pack.

In addition the above mentioned Bowie-Dick-Simulation-Test fulfills all requirements for the test system in steam sterilization processes described in the European standard EN 867-5 “Hollow Load” to the full extent and exceeds the air removal sensitivity of the above mentioned reference test device “Hollow Load” in fractionated vacuum cycles.

The “Hollow Load” test has been integrated in the European standard for steam sterilizers EN 285:2008 as an additional type test.

If another process challenge device (PCD) or indicator strips (indicator systems) than the one described above is used, the test results are not comparable and this test report is not valid.

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

7 Annex

1. Test documentation air removal test – Comparison between gke BDS-Test and reference
2. Test sterilizer certificate
3. Calibration certificate of the steam test sterilizer
4. Calibration certificate of the dry heat sterilizer
5. Test/Quality certificate of the biological indicators
6. SAL accreditation certificate
7. SAL accreditation Scope
8. License of the S2 laboratory
9. Product datasheet gke BDS

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☏ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

B1 Change of air removal
PCD-verification
according to ISO 11140-4

05.03.2008
Date

Signature

3,5 min at 134°C
Test-Sterilizer

Air removal	Sterilization batch	Compact blue	Standard test pack	
4 x 50 - 970 mbar	3326		PASS	
			PASS	
			PASS	
4 x 140 - 970 mbar	3342		PASS	
			PASS	
			PASS	
4 x 160 - 970 mbar	3356		FAIL	
			FAIL	
			FAIL	

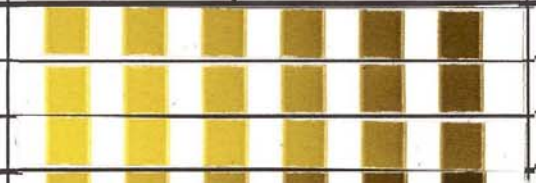
Steam gradient: 450 mbar/min
Vacuum gradient: 450 mbar/min
Indicator batch: 071015

B1 Induces leakage
PCD-verification
according to ISO 11140-4

06.03.2008
Date

Signature

3,5 min at 134°C
Test-Sterilizer

Leakage	Sterilization batch	Compact blue	Standard test pack	
40 Liter/ h	3394			
30 Liter/ h	3397			
20 Liter / h	3398		FAIL	
			FAIL	
			FAIL	
10 Liter / h	3401		PASS	
			PASS	
			PASS	

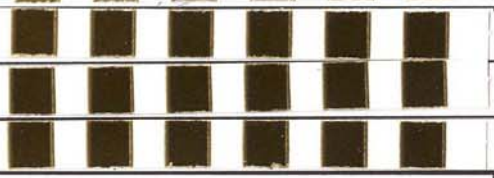
Steam gradient: 450 mbar/min
Vacuum gradient: 450 mbar/min
Indicator batch: 071015

B1 Air injection
PCD-verification
according to ISO 11140-4

07.03.2008
Date

Signature

3,5 min at 134°C
Test-Sterilizer

Air injected	Sterilization batch	Standard test pack	Compact blue	
150 ml	3399	FAIL		
		FAIL		
		FAIL		
100 ml	3387	PASS		
		PASS		
		PASS		

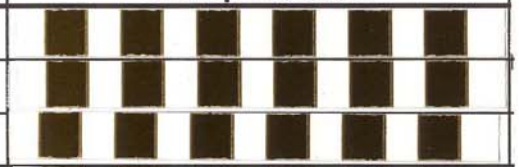
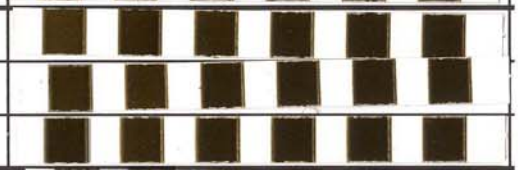
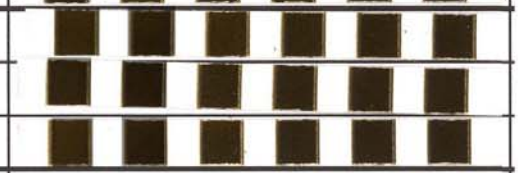
Steam gradient: 450 mbar/min
Vacuum gradient: 450 mbar/min
Indicator batch: 071015

Equivalence test accodring to EN 867-5

04.03.2008
Date

Signature

3,5 min at 134°C
Test-Sterilizer

Air removal	Sterilization batch	Compact blue
9 x 200 - 950 mbar PASS	3180	
9 x 200 - 950 mbar PASS	3184	
9 x 200 - 950 mbar PASS	3185	

Steam gradient: 450 mbar/min
Vacuum gradient: 450 mbar/min
Indicator batch: 071015

Modified air removal
Equivalence test
according to EN 867-5

04.03.2008
Date

Signature

3,5 min at 134°C
Test-Sterilizer

Air removal	Sterilization batch	Hollow A Helix	Compact blue
9 x 460 - 950 mbar	3240	⊕	
		⊕	
		⊖	
9 x 450 - 950 mbar	3242	⊖	
		⊖	
		⊖	
9 x 440 - 950 mbar	3257	⊖	
		⊖	
		⊖	
9 x 430 - 950 mbar			
9 x 420 - 950 mbar	3254		
9 x 410 - 950 mbar	3256		
9 x 400 - 950 mbar			
9 x 390 - 950 mbar	3248		
	~~3273~~		
9 x 380 - 950 mbar	3235		
9 x 370 - 950 mbar	3246		
9 x 360 - 950 mbar	3231		
9 x 350 - 950 mbar	3233		
9 x 340 - 950 mbar	3234		
9 x 330 - 950 mbar	3227		
9 x 320 - 950 mbar	3232		
9 x 310 - 950 mbar	3225		
9 x 300 - 950 mbar	3222		
9 x 290 - 950 mbar	3221		
9 x 280 mbar - 950	3226		

Steam gradient: 450 mbar/min
Vacuum gradient: 450 mbar/min
Indicator batch: 071015

F&M Lautenschläger

F.&M. LAUTENSCHLÄGER GmbH & Co. KG · Postfach 501260 · D-50972 Köln

gke - GmbH

Auf der Lind 10

65529 Waldems

Zum Engelshof 1
50996 Köln / Rodenkirchen
Tel.: +49 221/35017-0
Fax: +49 221/35017-15 (Zentrale)
Fax: +49 221/35017-10 (Einkauf)
info@lautenschlaeger.net
www.lautenschlaeger.net

W. Dächsel
Tel.: 0221 / 35017-45
27.06.2008 07/dä

Certificate

We confirm that the steam exposure apparatus

manufacturer:	F. & M. Lautenschläger, Zum Engelshof 1-5, 50996 Köln,
type:	Prüfsterilisator ZENTRACERT 3119
serial number:	1144
year of manufacture:	1995 – refurbished 2007

complies with all requirements published in the standards:

EN 285 : 2008
Sterilization – Steam-sterilizers – Large sterilizers

Except clauses 7.1.1, 7.1.12, 7.2.1, 10, 15-20, 22, 23 and the related information in 25 and 26, because the sterilizer can be programmed individually.

EN ISO 11140-3: 2007
Sterilization of health care products – Chemical indicators – Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

- Annex H (steam exposure apparatus)

EN ISO 11140-4 : 2007
Sterilization of health care products – Chemical indicators – Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration

- Annex J (Steam exposure apparatus and steam for test purposes)

F. & M. Lautenschläger GmbH & Co. KG

Calibration Certificate

Certificate	Certificate no.:	**082041**
	Calibration date:	2008-04-21
	Tester:	Philipp Kloos
	Test:	**Temperature and pressure test**
Test item	Name:	Test sterilizer
	Inventory no.:	330-009 P
	Manufacturer:	Lautenschläger
	Type no.:	3119
	Year of manufacture:	1995
	Installation location:	SAL Technical Center
	Last calibration:	2007-07-16
	Precision:	*Temperature* PT100 Class A $\Delta T = \pm (0{,}15\ °C + 0{,}002 \cdot T)$ Determined maximum tolerance: ± 0,1°C from set value *Pressure* Determined maximum tolerance: ± 5 mbar at 50 mbar chamber pressure and 10 mbar at 3000 mbar chamber pressure
	Picture	

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☎ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • 📠 info@sal-gmbh.com

Test apparatus temperature	Name:	Calibration oven
	Inventory no.:	330-010 P
	Manufacturer:	Isotech
	Last manufacturer calibration:	2006-06-01
	Precision:	ΔT = ± 0,03 °C (set value to actual value)
	Picture	
Test apparatus pressure	Name:	Pressure Sensor 0 – 400 mbar
	Inventory no.:	330-013 P
	Manufacturer:	Wika
	Last manufacturer calibration:	2007-08-10
	Precision:	ΔP= ± 0,1 mbar (für 0 - 400 mbar)
	Picture	
	Name:	Pressure Sensor
	Inventory no.:	330-014 P
	Manufacturer:	Jumo
	Last manufacturer calibration:	2007-08-10
	Precision:	ΔP= ± 0,2 mbar (for 0 - 4000 mbar)
	Picture	

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☎ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

DESIGN, VALIDATION AND MONITORING OF STERILIZATION-PROCESSES AND -INSTRUMENTS

Sterility Assurance Laboratories

Environmental conditions

Temperature: 22,5 °C

Pressure: 980 mbar

Data logging Temperature

Set point (measuring point calibration oven)	*Test*			*Average value*
	1	*2*	*3*	
134,0°C	133,9°C	134,0°C	134,0°C	134,0°C
60,0°C	60,1°C	60,0°C	60,0°C	60,0°C

Tolerance Temperature

Measuring point	*Normal*	*Test item*	*Δ T*	*ΔT_{max} according specification*
134°C	134,0°C	134,0°C	0,0°C	0,1°C
60°C	60,0°C	60,0°C	0,0°C	0,1°C

Data logging Pressure

Set point (measuring point pressure sensor)	*Test*			*Average value*
	1	*2*	*3*	
~3060 mbar	3087 mbar	3087mbar	3088 mbar	3087 mbar
~45 mbar	44 mbar	44 mbar	44 mbar	44 mbar

Tolerance Pressure

Measuring point	*Normal*	*Test item*	*Δ P*	*ΔP_{max} according specification*
~3060 mbar	3085 mbar	3087 mbar	2 mbar	10 mbar
~45 mbar	43 mbar	44 mbar	1 mbar	5 mbar

Calibration results

X	Measured values ***conform*** *to the specifications*
	Measured values ***do not conform*** *to the specifications*

Next calibration April 2009

Glashuetten, 2008-04-21

Philipp Kloos

Assistance Laboratory

SAL GmbH • Feldstr. 14 • D-61479 Glashütten • ☎ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • e-mail info@sal-gmbh.com

Calibration Certificate

Certificate	Certificate no.:	**082062**
	Calibration date:	10.07.2007
	Tester:	Philipp Kloos
	Test:	**Temperature test**
Test item	Name:	Dry heat sterilizer
	Inventory no.:	330-006 P
	Manufacturer:	Memmert
	Type no.:	ULP 500
	Year of manufacture:	2000
	Installation location:	SAL Technical Center
	Last Calibration:	2006-07-17
	Precision:	*Temperature* PT100 Class B $\Delta T = \pm (0{,}30\ °C + 0{,}005 \cdot T)$ Determined maximum tolerance: ± 1,0°C from set value
	Picture	

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☎ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

Test apparatus temperature

Name:	Multi channel writer
Inventory no.:	330-004 P
Manufacturer:	Eurotherm Chessel
Type:	4250 M
Last manufacturer calibration:	--- (new calibration before each measurement)
Precision:	ΔT = ± 0,15 °C (set value to actual value)

Picture

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☎ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

Environmental conditions

Temperature: 26,5 °C

Pressure: 991 mbar

Temperature measuring

Measuring point	*Test item*	*Normal*	*Δ T*	*ΔT_{max}*	*OK?*
60 °C	60°C	60,03 °C	0,03 °C	1 °C	Yes
140 °C	140°C	137,38 °C	2,62 °C	1 °C	No
160 °C	160°C	156,66 °C	3,34 °C	1 °C	No

Correction

Set value	*Set value temperature*
60 °C	60 °C
141 °C	140 °C
164 °C	160 °C

Temperature measuring (after correction)

Measuring point	*Test item*	*Normal*	*Δ T*	*ΔT_{max}*	*OK?*
60 °C	60°C	60,05 °C	0,05 °C	1 °C	Yes
140 °C	141°C	140,33 °C	0,33 °C	1 °C	Yes
160 °C	164°C	16,09 °C	0,09 °C	1 °C	Ja

Calibration result

X	Measured values ***conform*** *to the specifications*
	Measured values ***do not conform*** *to the specifications*

Next Calibration July 2008

Glashütten, 2007-07-17

Philipp Kloos

Assistance Laboratory

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten • ☎ +49-(0)6082-3087 • 🖷 +49-(0)6082-3080 • ✉ info@sal-gmbh.com

gke *specializing in sterilization design, validation and monitoring*

gke-Steri-Record®-Bio-Indicator-D-K

Geobacillus[1] *stearothermophilus* Spore Strips
Recommended for use in steam sterilization processes.

Certificate of Analysis

This document certifies that the Biological Indicators for this lot meet the ***gke***'s Quality Control Specifications and performance parameters published in the current United States Pharmacopoeia (USP) and the EN 866 and ISO 11138 standards as indicated below.

Waldems-Esch, 2007-10-09

***gke*-GmbH**
K. Tobisch
-Laboratory-

Performance Data for Lot: 316 7362 **Expiry Date: 10/2009**

Organism Geobacillus[1] *stearothermophilus* ATCC™ 7953[2]

Mean Strip Recovery	**2,0 x 10^6**	**[CFU]**	Colony Forming Units/Strip
D $_{121°C\ Steam}$ Value	**1,6**	**[min.]**	Saturated steam by linear regression
z $_{Steam}$ Value	**9,7**	**[°C]**	tested at 118, 121, 126°C
F-Bio $_{121°C}$ Value	**10,1**	**[min.]**	= Log Pop. x D-value; Sterilization time to achieve 10^0 CFU

The standard ISO 11138 requires a $F_{BIO121°C}$-value of at least 7,5 min when monitoring steam sterilization processes with a F_0-value of 15 min minimum. All values are determined at time of manufacture. The resistance values are tested with a resitometer according to EN 866. The values are reproducible only under the exact conditions under which they were determined.

[1] Strain ATCC™ 7953 is now called Geobacillus *stearothermophilus* (formerly Bacillus *stearothermophilus*).
[2] ATCC™ is the registered trade mark of American Type Culture Collection.

Resistance-Characteristic

Survival Time [min.] > (labeled D value) x ($\log_{10}$ labeled spore count per carrier - 2)
Kill Time [min.] < (labeled D value) x ($\log_{10}$ labeled spore count per carrier + 4)

Longterm Stability

The population of ***gke*-*Steri-Record®*-spore strips** are tested every 6 month. Until now the unchanged production of strips reached always at the expiry date a recovery rate above 90%.

Instruction for use

1. Include ten biological indicators with each sterilizer cycle monitored. Place in the most difficult to sterilize chamber locations.
2. After sterilization, aseptically transfer the spore strip into 10 ml sterile Tryptic Broth.
3. It is recommended that an unsterilized control strip be run daily to confirm spore viability and media growth promoting properties. Also culture Media without spore strips to check culture media and vial properties. GROWTH SHOULD BE EVIDENT IN CONTROL TUBES IN 2 DAYS.
4. Incubate sterilized spore strips for 7 days at 55-60°C.
5. Observe all tubes daily for growth. Gram stain all positives. Gram positive rods are indicative of the indicator organisms.
6. Record results.
7. If a positive result is observed, repeat the test procedures, placing several indicators throughout the sterilizer.
8. If a positive result is again observed, have the sterilizer examined for malfunction.
9. Store below 30°C and 70% relative humidity, away from sterilizing agents.
10. Do not use after expiry date. Incinerate.

***gke*-GmbH Auf der Lind 10 D-65529 Waldems / Germany ☎ +49 (0)6126-9432-0 -10 info@gke.eu**

Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

Baden-Württemberg

Bayern

Berlin

Brandenburg

Bremen

Hamburg

Hessen

Mecklenburg-Vorpommern

ACCREDITATION

The **Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices** (ZLG) confirms that the testing laboratory

SAL Sterility Assurance Laboratories GmbH

Feldstrasse 14
61479 Glashütten
Germany

is competent under the terms of

Council Directives 93/42/EEC, 90/385/EEC and EN ISO/IEC 17025

for

microbiological-hygienic testing including physical testing of medical devices, Process-Challenge-Devices, washer-disinfectors and sterilization processes; environmental monitoring

This accreditation is valid up to **13.11.2012**.

This document is valid only in conjunction with the accreditation notice. Its annex in force is part of this document.

Registration number **ZLG-P-403.07.07**

Bonn, 04.03.2008

Dr. Undine Soltau
Director of ZLG

Thüringen

Schleswig-Holstein

Sachsen

Sachsen-Anhalt

Saarland

Rheinland-Pfalz

Nordrhein-Westfalen

Niedersachsen

Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

ZLG

Attachment 1 to the notification dated 2007-11-14 about the

Accreditation

of SAL Sterility Assurance Laboratories GmbH
Feldstraße 14
D-61479 Glashütten
Germany

General Manager Danja Kaiser

as Test Laboratory for Medical Devices according the EU-Directives 93/42/EWG[1], 90/385/EWG[2] and EN ISO/IEC 17025[3]

Technical Manager Jörn Gömann

Phone +49 (0)6082-3087

Fax +49 (0)6082-3080

E-Mail info@sal-gmbh.com

Website www.sal-gmbh.com

Reg.-No. **ZLG-P-403.07.07**

Scope

Testing category	**Tested products Device category**	**Test method** Test type	**Standard method of testing**
Microbiological hygienic Tests	Medical devices	Testing the resistance of reference germs depending on the characteristics of medical devices and sterilization with – steam – dry heat – ethylene oxide – formaldehyde – hydrogen peroxide	EN ISO 11138-1 PA 6.1-01-10 PA 6.1-02-01 PA 6.1-02-02 PA 6.1-02-03 PA 6.1-02-04 PA 6.1-02-05 PA 6.1-02-09
		Sterility test – membrane filtration – direct inoculation	EN ISO 11737-2 PA 6.1-10-05 PA 6.1-10-06

Testing category	**Tested products Device category**	**Test method** Test type	**Standard method of testing**
Microbiologic hygienic tests including physical tests	Sterilization procedure	Validation and routine monitoring of sterilization processes with	
		– Moist heat	EN ISO 17665-1 EN 554 VA 6.3-30 PA 6.3-30-01 PA 6.3-30-02 PA 6.3-30-03 *Further applicable:* EN 13060 EN 285 EN 285/A1 58951
		– Dry heat	EN ISO 14937 VA 6.3-3
		– Ethylene oxide	EN ISO 11135-1 EN 550 VA 6.3-32 *Further applicable*: EN ISO 14937 EN 1422
		– Low temperature steam and formaldehyde (NTDF)	EN 14180 EN 15424 VA 6.3-33
		– Hydrogen peroxide	EN ISO 14937 VA 6.3-34
	Washer disinfectors (WD) – with thermal disinfection for surgical instruments, anaesthetic devices, containers, paraphernalia, glass device	Validation Routine testing	EN ISO 15883-1 EN ISO 15883-2 VA 6.3-10 PA 6.3-10-04

Testing category	**Tested products Device category**	**Test method** Test type	**Standard method of testing**
Microbiologic hygienic tests including physical tests	Washer-disinfectors (WD)		
	– with chemical or thermal disinfection for thermolabile endoscopes	Validation Routine testing	EN ISO 15883-1 EN ISO 15883-4 VA 6.3-10 PA 6.3-10-03 PA 6.3-10-04 PA 6.3-10-05 *Further applicable:* Robert-Koch-Institute (RKI)-Guidance Testing of thermal disinfection procedures in washer-disinfectors
	Medical devices, information for reprocessing	Testing the provided information within the validation for	
		– Cleaning	EN ISO 17664 VA 6.3-10
		– Disinfection	EN ISO 17664 VA 6.3-02 VA 6.3.10 PA 6.1-10-01
		– Sterilization with • Moist heat • Dry heat • Ethylene oxide • Formaldehyde • Hydrogen peroxide	EN ISO 17664 VA 6.3-02 VA 6.3-30 VA 6.3-31 VA 6.3-32 VA 6.3-33 VA 6.3-34
		– Drying	EN ISO 17664 VA 6.3-02
		– Packaging/Storing	EN ISO 17664 VA 6.1-04

Testing category	**Tested products Device category**	**Test method** Test type	**Standard method of testing**
Microbiologic hygienic tests	washing and disinfection procedures	**Testing with biological indicators**	
		– Washer-disinfectors for thermolabile endoscopes	EN ISO 15883-4 VA 6.3-10 PA 6.3-10-01 PA 6.3-10-02 *Further applicable:* EN ISO 15883-1 VA 6.3-10
	Test systems Biological indicators	Tests to prove compliance	USP 29:2006 [55]
		– Vitality	PA 6.1-01-04
		– Population determination of spore suspensions	PA 6.1-01-02
		– Population determination of spores on solid carriers	PA 6.1-01-03
		– Purity	PA 6.1-01-05
		– Germ identity	PA 6.1-01-06
		D-value determination and quantitative evaluation for sterilization processes using	
		• Moist heat	EN ISO 11138-3
		• Dry heat	EN ISO 11138-4
		• Ethylene oxide	EN ISO 11138-2
		• Low-temperature-steam-formaldehyde	EN ISO 11138-5 PA 6.2-01-01 bis –10 PA 6.2-02-01 bis –09
		• Hydrogen peroxide	*Further applicable:* EN ISO 11138-1

Testing category	**Tested products Device category**	**Test method** Test type	**Standard method of testing**
Microbiologic hygienic tests	Test systems Chemical indicators	Tests to prove compliance in sterilization processes using – Moist heat – Dry heat – Ethylene oxide – Low-temperature-steam-formaldehyde – Hydrogen peroxide	EN ISO 11140-1 EN ISO 11140-3 EN ISO 11140-4 PA 6.2-01-01 bis -12 AA 6.2-01-13
	Medical Device Simulators (MDS) and Batch Monitoring Systems (BMS)	Testing to prove applicability of	
		– Bowie-Dick-Simulation-Tests	EN ISO 11140-4 PA 6.2-10-03
		– Test devices according EN 867-5	EN 867-5 PA 6.2-10-04 PA 6.2-10-05 PA 6.2-10-06
		– Test devices according DIN EN 1422	EN 1422 PA 6.2-10-07
		– Medical Device Simulators (MDS)	PA 6.2-10-08
		– Batch Monitoring Systems (BMS)	PA 6.2-10-09
	Sterile barrier and packaging systems Materials	Tests to prove compliance	
		– Compatibility with moist heat or dry heat	EN ISO 11607-1 EN 868-5 AA 6.1-04-01
		– Suitability for storage and transport	EN ISO 11607-1 EN 868-5 AA 6.1-04-02
		– Colour change of the process indicator	EN 868-5 Paragraph 4.4 EN ISO 11140-1 PA 6.3-50-06

Testing category	**Tested products Device category**	**Test method** Test type	**Standard method of testing**
Microbiologic hygienic tests	Sterile barrier and packaging systems Materials	Tests to prove compliance	
		– of plastic laminated film for capillary holes	EN 868-5 PA 6.1-04-05
		– Peel characteristics of paper-plastic-laminates	EN 868-5 PA 6.1-04-06
		– Stability of the heat sealed joint	EN 868-5 PA 6.1-04-08 PA 6.1-04-09
	Environmental control of the production and testing on the hygienic conditions of the products according EN ISO 13485: 2003, Para. 6.4 and Para. 7.5		
	Medical devices Biologic materials	Estimation of the population of microorganisms on products (Bioburden determination)	EN ISO 11737-1 Ph. Eur. 5, 2.6.12 USP 30 [61]
		– Membrane filtration method	
		– Spread plate method	
		– Pour plate method	

Complex of rules

EN 285 : 2006-08 EN 285/A1 : 2006-09	Sterilization – Steam sterilizers – Large sterilizers
EN 556 : 1994-12	Sterilization of medical devices – Requirements for medical devices to be labelled „Sterile“
EN 867-5 : 2001-11	Non-biological systems for use in sterilizers – Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S
EN 868-1 : 1997-02	Packaging materials and systems for medical devices which are to be sterilized – Part 1: General requirements and test methods
EN 868-5 : 2002-01	Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – Requirements and test methods
EN 1422 : 1997-11	Ethylene oxide sterilizers - Requirements
EN ISO 11135-1 : 2007-08	Sterilization of health care products – Ethylene oxide – Part 1: Requirements fort he development, validation and routine control of a sterilization process for medical

	devices
EN ISO 11138-1 : 2006-09	Sterilization of health care products – Biological indicators – Part 1: General requirements
EN ISO 11138-2 : 2006-10	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11138-3 : 2006-10	Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes
EN ISO 11138-4 : 2006-09	Sterilization of health care products – Biological indicators – Part 4: Biological indicators for dry heat sterilization processes
EN ISO 11138-5 : 2006-09	Sterilization of health care products – Biological indicators – Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes
EN ISO 11140-1 : 2006-04	Sterilization of health care products – Chemical indicators – Part 1: General requirements
EN ISO 11140-3 : 2006-12	Sterilization of health care products – Chemical indicators – Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
EN ISO 11140-4 : 2006-12	Sterilization of health care products – Chemical indicators – Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration
EN ISO 11140-5 : 2006-12	Sterilization of health care products – Chemical indicators – Part 5: Class 2 indicators for Bowie and Dick-type air removal tests
EN ISO 11140-3 : 2007-07	Sterilization of health care products – Chemical indicators – Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
EN ISO 11737-1 : 2006-08	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2 : 2000-04	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
EN 13060 : 2004-09	Small steam sterilizers
EN 14180 : 2003-10	Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing
EN ISO 14937 : 2001-05 EN ISO 14937/A1 : 2005-06	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process
EN 15424 : 2006-10	Sterilization of medical devices – Development, validation and routine control of sterilization processes – Low temperature steam and formaldehyde
EN ISO 15883-1 : 2006-07	Washer-disinfectors – Part 1: General requirements,

	definitions and tests
EN ISO 15883-2 : 2006-07	Washer-disinfectors – Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware, etc.
EN ISO 15883-3 : 2006-07	Washer-disinfectors – Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
EN ISO 15883-4 : 2005-06	Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
EN ISO 17664 : 2004-07	Sterilization of medical devices – Information to be provided by the manufacturer fort he processing of resterilizable medical devices
EN ISO 17665-1 : 2006-11	Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 18472 : 2006-10	Sterilization of health care products – Biological and chemical indicators – Test equipment
EN 20187 : 1993-11	Paper, board and pulps; standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples
58951-2 : 2003-07	Sterilization - Steam sterilizers for laboratory use – Part 2: Apparatus requirements, requirements on services and installation
58953-6 : 1987-01	Sterilization; sterile supply; handling of plain an creped sterilization paper
Ph. Eur. 5, 2.6.12	Count of all augmentable germs
USP 30 : 2006 [55]	Biological Indicators: Resistance Performance Tests
USP 30 : 2006 [61]	Microbial Limit Tests
PA 6.1-01-02	Population determination in spore suspensions
PA 6.1-01-03	Population determination on spore strips
PA 6.1-01-04	Vitality determination of spore strips
PA 6.1-01-05	Population determination in test tubes
PA 6.1-01-06	Purity determination of biological indicators
PA 6.1-01-07	Gram colouring test
PA 6.1-01-08	Spore colouring according to Wirtz
PA 6.1-01-09	Determination of the germ identity
PA 6.1-01-10	Determination of the growth inhibition on solid samples
PA 6.1-02-01	Resistance determination – Steam
PA 6.1-02-02	Resistance determination – Dry heat
PA 6.1-02-03	Resistance determination – Ethylene oxide

PA 6.1-02-04	Resistance determination – Hydrogen peroxide
PA 6.1-02-05	Resistance determination – Formaldehyde
PA 6.1-02-06	z-value determination
PA 6.1-02-07	D-value determination according to the Fraction Negative Method
PA 6.1-02-08	Determination of the survival window
PA 6.1-02-09	D-value determination for germs in suspensions
VA 6.1-04	Testing sterile barrier systems (SBS)
AA 6.1-04-01	Testing sterile barrier systems for sterilizability
AA 6.1-04-02	Testing sterile barrier systems for storability and transportability
PA 6.1-04-03	Process indicator test on sterile barrier systems
PA 6.1-04-05	Testing sterile barrier integrity of sterile barrier systems
PA 6.1-04-06	Determination of the Peel characteristics of sterile barrier systems
PA 6.1-04-08	Determination of the stability of the stability of the dry heat-sealed joint of sterile barrier systems
PA 6.1-04-09	Determination of the stability of the moist heat-sealed joint of sterile barrier systems
VA 6.1-10	Qualification of medical devices: Determination of the bioburden
	Inoculation and validation of the recovery
PA 6.1-10-04	Population determination on a product
PA 6.1-10-05	Sterility test with membrane filter test
PA 6.1-10-06	Sterility test by direct inoculation
VA 6.2-01	Testing of chemical indiators
PA 6.2-01-01	Testing of completeness of the manufactur’s instructions
PA 6.2-01-02	Testing of readability of the indicator labeling before and after sterilization
PA 6.2-01-04	Testing of size, form and indicator print
PA 6.2-01-05	Testing of the relative refexion density
PA 6.2-01-06	Stability test of an indicator
PA 6.2-01-07	Testing of chemical indicators for bleeding
PA 6.2-01-08	Colour change test of chemical indicators for steam sterilization
PA 6.2-01-09	Colour change test of chemical indicators for dry heat sterilization
PA 6.2-01-10	Colour change test of chemical indicators for ethylene oxide sterilization
PA 6.2-01-11	Colour change test of chemical indicators for

	formaldehyde sterilization
PA 6.2-01-12	Colour change test of chemical indicators for H_2O_2-/ plasma sterilization
AA 6.2-01-13	Accelerated aging for chemical indicators
PA 6.2-10-03	Testing of standard conformity of a Bowie-Dick-Simulation-Test according ISO 11140-4
PA 6.2-10-04	Testing the PCD dimensions according EN 867-5
PA 6.2-10-05	Compatibility test of the PCD materials according EN 867-5
PA 6.2-10-06	Performance test of PCDs according EN 867-5
PA 6.2-10-07	Testing of the dimensions and materials of the norm test device according DIN EN 1422
PA 6.2-10-08	Conformity test of a medical device simulator (MDS)
PA 6.2-10-09	Conformity test of a batch monitoring system (BMS)
VA 6.3-02	Validation of reprocessing medical devices according ISO 17664
VA 6.3-10	Validation of washing, disinfection and drying processes
PA 6.3-10-04	Determination of the protein amounts of blood contaminations
PA 6.3-10-05	Vitality tests of PCDs with E. faecium test contamination
PA 6.3-10-06	Determination of the bioburden of a process water
VA 6.3-20	Validation of heat-sealed joint processes
VA 6.3-30	Validation of steam sterilization processes
PA 6.3-30-01	Testing steam quality for non condensable gases
PA 6.3-30-02	Testing steam quality for dryness
PA 6.3-30-03	Testing steam quality for superheation
VA 6.3-31	Validation of dry heat sterilization processes
VA 6.3-32	Validation of ethylene oxide sterilization processes
VA 6.3-33	Validation of formaldehyde sterilization processes

Abbreviations

AA	SOP = Standard Operating Procedure
DIN	German Standard organization (Deutsches Institut für Normung)
EN	European standard (Europäische Norm)
ISO	International Organisation for Standardization
Ph. Eur.	European Pharmacopeia
PA	Test instruction (Prüfanweisung)
USP	United States Pharmacopeia
VA	Process instruction (Verfahrensanweisung)

Approved signatories

Ms. Danja Kaiser	All areas
Mr. Jörn Gömann	All areas

[1] Guidance 93/42/EEC of the council of June 14, 1993 about medical devices, Official journal of the European Community No. L 169 dated 1993-07-12, p. 1; last modified by guidance 2007/47/EG dated 2007-09-05, Official journal No. L 247/21 dated 2007-09-21, p. 1

[2] Guidance 90/385/EWG of the council of June 20, 1990 to adapt the regulations of the member states about medical devices for active implantation. Official journey of the European Community No. L 189 dated 1990-07-20, p. 17, last modified by guidance 2007/47/EG of September 5, 2007, Official Journal No. L 247/21 dated 2007-09-21, p. 1

[3] DIN EN ISO/IEC 17025 : 2005-08 General requirements for the competence of testing and calibration laboratories

Gesundheitsamt
Bad Schwalbach
Heimbacher Str. 7
65307 Bad Schwalbach

ERLAUBNISBESCHEID

FÜR DIE TÄTIGKEIT MIT KRANKHEITSERREGERN

NACH DEM INFEKTIONSSCHUTZGESETZ

Herr Dipl. Biologe Jörn Gömann
geb. am 6. Mai 1965 in Bremen

Hiermit wird auf der Grundlage des § 44 Infektionsschutzgesetz (IfSG) in der derzeit geltenden Fassung die Erlaubnis erteilt, Krankheitserreger in den Geltungsbereich dieses Gesetzes zu verbringen, sie auszuführen, sie aufzubewahren, abzugeben oder mit ihnen zu arbeiten.

Die Erlaubnis wird gemäß § 47 Abs. 3 (IfSG) eingeschränkt auf den Umgang mit Enterococcus faecium und Pseudomonas aeruginosa der Risikogruppe 2 (Definition gemäß § 3 Biostoffverordnung in der derzeit geltenden Fassung).

Die Erlaubnis erstreckt sich nicht auf den direkten oder indirekten Nachweis eines Krankheitserregers für die Feststellung einer Infektion oder übertragbaren Krankheit gemäß § 47 Abs. 4 IfSG.

Die erforderliche Sachkenntnis wurde

1. nach abgeschlossenem naturwissenschaftlichem Studium mit mikrobiologischen Inhalten durch die Vorlage des Diplom-Zeugnisses der Universität Stuttgart vom 23. März 1995 belegt und
2. mit der hauptberuflichen Tätigkeit als wissenschaftlicher Mitarbeiter bzw. Laborleiter auf dem Gebiet der Mikrobiologie/Technik für den Zeitraum von 1995 bis 2008 bestätigt.

Die Erlaubnis kann bei Vorliegen eines Versagungsgrundes nach § 47 Abs. 1 IfSG gemäß § 48 IfSG widerrufen werden.

Die Anzeigepflicht nach § 49 IfSG bleibt von dieser Erlaubnis unberührt.

Bad Schwalbach, den 22.04.2008 Im Auftrag

RHEINGAU-TAUNUS-KREIS KREISGESUNDHEITSAMT 3

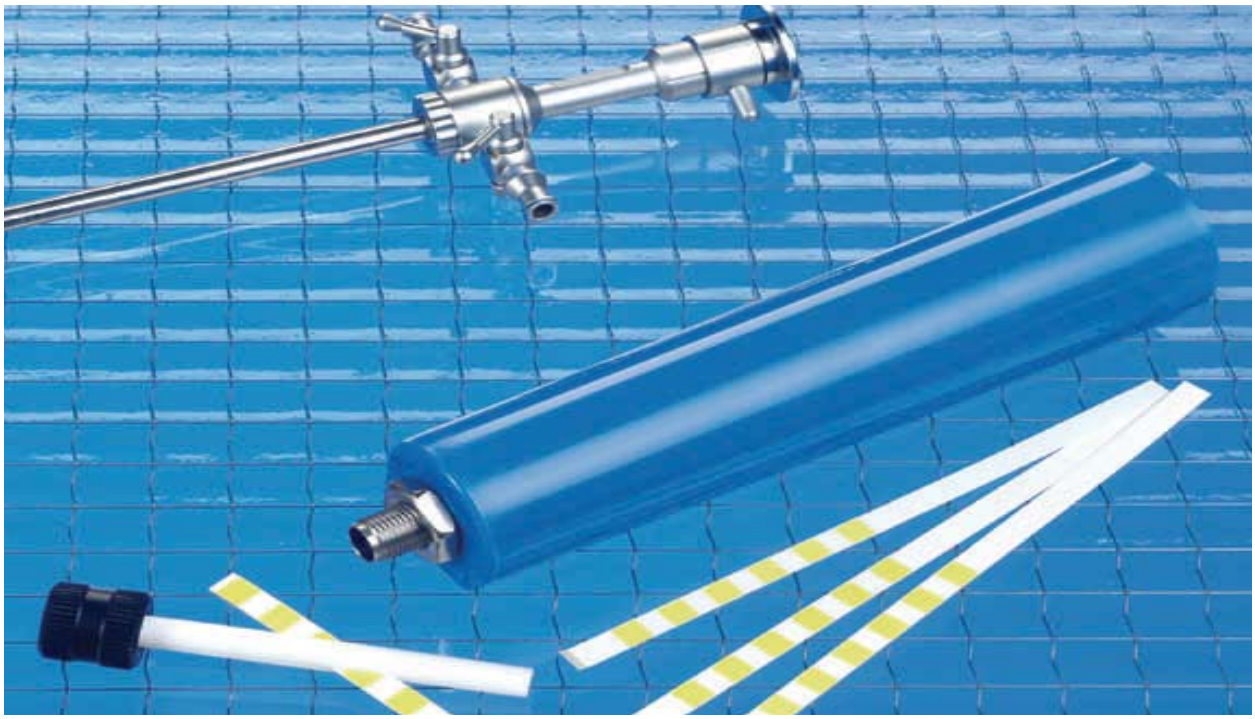
Dr. Christina Klein
Ärztin für öffentliches Gesundheitswesen

Rechtsbehelfsbelehrung:
Gegen diese Erlaubnis kann innerhalb eines Monats nach Bekanntgabe Klage beim Verwaltungsgericht Wiesbaden, Konrad-Adenauer-Ring 15, 65187, Wiesbaden, schriftlich oder zur Niederschrift des Urkundsbeamten der Geschäftsstelle erhoben werden. Die Klage muss den Kläger, den Beklagten und den Streitgegenstand bezeichnen. Sie soll einen bestimmten Antrag enthalten. Die zur Begründung dienenden Tatsachen und Beweismittel sollen angegeben werden. Die angefochtene Verfügung soll in Urschrift oder in Abschrift beigefügt werden. Der Klage nebst Anlagen sollen so viele Abschriften beigefügt werden, dass alle Beteiligten eine Ausfertigung erhalten können.

gke *Steri-Record*® Bowie-Dick-Simulation and Helix-Test

STEAM

for complex hollow and solid instruments and porous loads



gke *Steri-Record*® Bowie-Dick-Simulation-Test (Compact-PCD-Version)

Product description

The gke-*Steri-Record*® Bowie-Dick-Simulation (BDS) test is a class 2 indicator according to EN ISO 11140-1 consisting of a "specific test load" (PCD) and an "indicator system" (indicator strip) inside.
It consists of a Process Challenge Device (PCD) with an external highly durable case containing an internal stainless steel tube connected with a capsule holding the indicator.
The highly durable PCD can be used for several thousand applications. There is only one indicator strip required for each test.

Performance characteristics

Due to the patented innovative "multi-stage" construction of the BDS test this test is fulfilling the requirements of two standards:

- Bowie-Dick porous cotton pack according to EN 285 checking the specifications with the test method described in EN ISO 11140-4
- Helix-Hollow-Load-Test "Hollow A" according to EN 867-5

Above tests have been approved by an accredited laboratory according to EN ISO 17025. (A test report is available on request.)
This test can replace the original Bowie-Dick porous cotton pack and the Helix-Test simultaneously.

Application

Those functional tests are called type tests verifying the specifications of sterilizer requirements but they are not sterility tests. This test checks the air removal and steam penetration capability of the sterilizer is achieved. It can be used in small sterilizers according to EN 13060 as well as in large sterilizers according to EN 285. Only sterilizers with sufficient air removal capabilities for hollow devices will pass this test. The European standard for large sterilizers has been updated in 2008 requesting the Bowie-Dick-Test according to EN 285 and the Helix-Test according to EN 867-5 as a type test. This test (gke *Steri-Record*® Chemo-BDS-C-H) replaces the two separately required type tests in EN 285. The BDS test is no substitution for routine monitoring. For routine monitoring indicators class 5 or 6 in each load or Batch-Monitoring-Systems (BMS) validated according to the load configuration must be used.

Operation description

If all six bars of the chemical indicator turn from yellow to black it is an indication of sufficient steam penetration inside the PCD. A positive result ensures that the sterilizer works according to the sterilizer specifications.

Sufficient temperature, time and steam penetration

Insufficient air removal and steam penetration

Temperature achieved, but no air removal and no steam penetration

Insufficient temperature, no air removal and no steam penetration

Benefits

- The innovative patented "multi-stage" design simulates the porous **gke** Bowie-Dick-Test according to EN 285 and the Helix-Test according to EN 867-5.
- This single test replaces the two type tests required in EN 285.
- The graduated colour change of the indicator bars informs about the magnitude of air removal and steam penetration inside the sterilizer and non-condensable gases in steam.
- Easy interpretation of the results due to precise colour change.
- The indicator colour chemistry is a non-reversible chemical reaction. The indicator strip can be documented proof for several years without changing back to its original colour.
- All **gke** chemical indicators are protected from bleeding by a polymer binder and surface coating and can be disposed with normal garbage.
- The innovate design and rationalized production provide a sensitive and cost effective test, where the PCD can be used for 5.000 - 10.000 cycles. Its specifications remain constant over the lifetime of the device.
- Convenient for 134°C– and 121°C-Bowie-Dick-Test programs according to EN 285.
- The Compact-PCD® can be used for many cycles. All important parts are made of stainless steel or thermal resistant polymers. Seals are replaced easily.
- Continuous reproducibility of the results over the lifetime of the PCD if seals are replaced precautiously.
- The test may be used in old sterilizers without Bowie-Dick Test programs and longer sterilization times without losing sensibility.
- The screw-cap consists of a highly thermal resistant material and stainless steel sandwich-construction that protects hands from high temperatures. The chemical indicator may be easily removed and evaluated on completion of each cycle.
- Environmentally friendly, no unnecessary waste.
- **gke** self-adhesive labels simplify recording with the **gke** *Steri-Record*® documentation system.

Order information

Each start-up kit contains one Compact-PCD® and 100 integrating indicator strips as well as a documentation sheet to be copied before daily use. Test devices are available separately as well. The indicator strips are available as refill packs without test devices containing one seal ring for the screw cap.

Art.-No.*	Product Code	Quantity	Content	Application
211-150	Chemo-D-BDS-1-C-H-EU Start-up kit	1 + 100	Compact-PCD® (colour: blue) integrating indicator strips	BDS test according to EN 285 including Helix-Test according to EN 867-5 "Hollow A" for hollow and solid instruments and also porous loads.
211-151	Chemo-D-BDS-PCD-C-H-EU	1	Compact-PCD® (colour: blue)	
211-111	Chemo-D-BDS-1	100	Integrating indicator strips, 1 seal ring	Refill pack with integrating indicator strips for all **gke**-BDS tests.
211-112	Chemo-D-BDS-2,5	250		
211-115	Chemo-D-BDS-5	500		

*All article numbers are supplemented with a three digit letter code providing the language, customized- or sample version.

gke GmbH
Auf der Lind 10
65529 Waldems-Esch / Germany
☎ +49 (0) 61 26 - 94 32- 0
🖷 +49 (0) 61 26 - 94 32- 10
✉ info@gke.eu
🌍 http://www.gke.eu

Your local **gke** sales partner