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Code of Practice

Testing Filling Machines of VDMA Hygiene Class V (Aseptic Plants): Sterilizing the Sterile Zone in a Machine Interior

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Code of Practice
Testing Filling Machines of VDMA Hygiene Class V (Aseptic Plants): Sterilizing the Sterile Zone in a Machine Interior

Content

This code of practice is the English translation of a publication which was drawn up by the VDMA Working Party for "Interface Problems in Aseptic Plants".

Suggestions concerning the contents of the code of practice may be sent to the Verband Deutscher Maschinen- und Anlagenbau e.V. (VDMA – German Engineering Federation), Fachabteilung Verpackungsmaschinen, Lyoner Straße 18, 60528 Frankfurt/M. (Fax: +49 69/6603-1211).

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Code of Practice
Testing Filling Machines of VDMA Hygiene Class V (Aseptic Plants): Sterilizing the Sterile Zone in a Machine Interior

Introduction to second edition

The first edition of this VDMA document was published in 2003. Next to editorial modifications the revision in 2014 comprises the amendments listed below:

- New title
- Update of references to standards and literature
- References to VDMA documents having been published since publication of the first edition have been included and definitions have been harmonized where necessary.
- Introduction of "Count-Reduction-Test" (section 5) as an alternative to "End point test" (section 4)

1 Introduction

Filling machines of VDMA hygiene class V (aseptic plants) are packaging machines which fill a commercial sterile product (e.g. food) without recontamination into a sterile pack, the latter usually having been sterilized in the machine.[1] To achieve this, high demands are imposed on the effectiveness of the devices for sterilizing the packaging materials, the sterile zone in the interior of the machine and the parts conveying the product (see VDMA Doc. Nr. 11). Thus, in packaging sterilization a count reduction of test microorganisms suitable for the sterilization method in question of at least four powers of ten is considered necessary. Equally high standards are set for the sterilization of the sterile zone in the interior of the machine.

The subject matter of this code of practice is the checking of the degree of microbiological effectiveness of devices for sterilizing the sterile zone in the interior of an aseptic filling machine. This involves a so-called challenge test requiring the artificial inoculation of the sterile zone in the interior of the machine with microorganisms.[2]

The starting point of the test is the successful completion of the machine cleaning operation. Once the sterile zone of the machine interior has been artificially inoculated with microorganisms the sterilization program of the filling machine is started and after this has finished, the number of surviving microorganisms is determined by means of a end-point test (section 4) or by means of a count-reduction test (section 5).

This code of practice does not extend to checking the maintenance of the aseptic state of the sterile zone of the interior of the machine during production.

The choice of test microorganisms suitable for the sterilization process in question is particularly important. The selection criterion is the resistance of the microorganisms and their spores to the sterilizing medium. Accordingly, this code of practice identifies test microorganisms regarded as suitable for checking sterilization methods introduced for aseptic plants at the time the code of practice went to press.

The sterilization performance of an aseptic filling machine depends on numerous machine parameters such as, inter alia, the concentration, the temperature and the contact time of the decontamination agent, the moisture content and temperature of the steam. These boundary conditions have to be specified prior to testing. The degree of effectiveness stated in the test report always relates to the boundary conditions established in advance. Accordingly, these must be recorded in the test report.

Extensive specialist knowledge is required for carrying out the test methods described here. The test methods should, therefore, be undertaken only by qualified persons.[3] It is recommended that the manufacturer of the machine to be tested be involved. It may be noted at this point that as a general principle only specialist microbiology staff should be entrusted with the procurement, storage and handling of the highly concentrated microbiological suspensions of test

[1] VDMA hygiene classes for filling machines for liquid and semi-liquid foods are introduced in VDMA Doc. No. 2 (2006)
[2] For an overview and a classification of microbiological tests for hygienic filling machines see VDMA Doc. No. 12 (2007)
[3] A list of institutes, laboratories and persons familiar with the test methods can be requested from the publisher of the code of practice.

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microorganisms needed for the test methods. The relevant safety regulations should be drawn to their attention.

The test methods described here may also be applied with appropriate modifications to checking other sterilization processes. See Section 7 with regard to this.

2 Definition of terms

Term	Definition	Notes
Hygienic filling machines of VDMA Class V (aseptic filling machines)	Packaging machines which fill a commercially sterile product of pH-value ≥ 4.6 free of recontamination into a package usually sterilized on the machine.	In order to achieve this, high demands are imposed on the effectiveness of the devices for sterilizing the packaging, the interior of the machine and parts conveying the product (see VDMA document Food Processing Machinery and Packaging Machinery No. 11/2006, formerly VDMA 8742). Thus in packaging sterilization, a count reduction of test microorganisms suitable for the sterilization method in question of at least four powers of ten is considered necessary. Aseptic filling machines are typically used for products of pH-value ≥ 4.6) which should have a relatively long shelf life without refrigeration.
Hygienic filling machines of VDMA Class IV	Packaging machines which fill a commercially sterile product with a pH-value < 4.6 free of recontamination into a package usually sterilized on the machine.	In order to achieve this, high demands are imposed on the effectiveness of the devices for sterilizing the packaging, the interior of the machine and parts conveying the product. However, these are less demanding than the requirements on Class V machines (see VDMA document Food Processing Machinery and Packaging Machinery No. 10/2005).
Commercially sterile product for filling	Filled product free of viable, pathogenic germs and free of microorganisms capable of reproducing in the product under normal, non-refrigerated conditions of storage and distribution.	

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Term	Definition	Notes
Commercially sterile packaging and accessories	Packaging and accessories free of viable, pathogenic germs and free of microorganisms capable of reproducing in the product under normal, non-refrigerated conditions of storage and distribution.	Defined on the basis of the FDA definition in 21 CFR 113[4]
Sterile zone in the machine interior	That region in the interior of an aseptic filling machine which after completion of sterilization must be kept free of germs in order to prevent recontamination of the sterile product during filling.	
Test microorganism	Microorganisms used to check the performance of decontamination devices	Test microorganisms should exhibit a high and - as far as possible - defined resistance to the sterilizing method being investigated. They should also be easy to detect and present no hazard to health. The description of a test microorganism should contain the following characteristics: name, precise designation of strain (ATTC No. or DSM No.), batch number (in the case of ready-made spore suspensions), D value, Z-value (where appropriate).
Inoculation	Artificial infection of a germ carrier with test microorganisms.	

3 Specification of test microorganisms for checking devices for sterilizing the sterile zone in the interior of aseptic filling machines

3.1 Sterilization by means of hydrogen peroxide

It is customary to use the spores of Bacillus atrophaeus (ATCC 9372, DSM 675, former Bacillus subtilis) and Bacillus subtilis SA 22 (identical to NCA 72-52 and DSM 4181)[5]

3.2 Sterilization by means of steam and dry heat

[4] "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable pathogenic microorganisms, as well as microorganisms of non-health significance, capable of reproducing in the food under normal non-refrigerated conditions of storage and distribution.

[5] Since the method of preparing the suspension of the spores has an effect on their resistance characteristics the production specification or the source of supply of the spore suspension should be noted in the test report. A check on the resistance of the spores to the sterilizing agent to be investigated is recommended. Sources of supply of spore suspensions are listed in Appendix III. Instructions for preparing the spore suspension of Bacillus subtilis SA22 may be found in Appendix II of this code of practice

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It is customary to use spores of the strain Bacillus stearothermophilus NCA 1518 (identical to DSM 5934) [6].[7]

3.3 Sterilization by means of peracetic acid

It is customary to use the spores of Bacillus atrophaeus (ATCC 9372, DSM 675, former Bacillus subtilis) and Bacillus subtilis SA 22 (identical to NCA 72-52 and DSM 4181)[8]

3.4 Media for suspending spores

Ethanolic solution (e.g. 70 %) or distilled water [9]. The concentration of the ethanolic solution and other additives are to be specified in the test report.

4 Test method - Germ carrier test – End-point-test

4.1 General procedure

In this test method germ carriers inoculated at three different concentration levels (for preparation see Appendix II) are affixed at points in the sterile zone of the machine interior relevant to the sterilization process.[10] After the sterilization program of the aseptic filling machine has finished the number of germ carriers employed which were left without growth of the respective test microorganism is determined for each concentration level.[11]

4.2 Test method

i) Prior to the test the points in the sterile zone of the machine interior relevant for sterilization and hence to be checked have to be identified. In doing so the involvement of the machine manufacturer is advisable.

ii) Provision of the required numbers of germ carriers respectively inoculated with 10^5, 10^4 and 10^3 test microorganisms (in addition 5 germ carriers for each level of dilution should be prepared to calculate the initial germ load.).[12]

iii) Introduction of the germ carriers into the clean and dry machine paying particular attention to the relevant positions for sterilization identified under i).

iv) Recording of the points occupied by germ carriers in the sterile zone of the machine interior.

[6] Sources of supply of spore suspensions are listed in Appendix III.
Since the resistance of the spores to moist heat may vary from batch to batch the D121 value and the method of calculating it should be stated in the test report. (For description of biological indicators of resistance to moist heat see EN ISO 14161.)
[7] Clostridium sporogenes PA (SC-218) is also employed for sterilization by means of steam.
[8] Since the method of preparing the suspension of the spores has an effect on their resistance characteristics the production specification or the source of supply of the spore suspension should be noted in the test report. A check on the resistance of the spores to the sterilizing agent to be investigated is recommended. Sources of supply of spore suspensions are listed in Appendix III. Instructions for preparing the spore suspension of Bacillus subtilis SA22 may be found in Appendix II of this code of practice.
[9] The test microorganisms should as far as possible be applied in distilled water or ethanolic solutions since use of buffers or common salt solution may give rise to high salt concentrations in the course of drying and any protective layers formed as a result may give a false, in this case a too low indication of killing rates.
[10] Ready-to-use germ carriers could be sourced from suppliers of spore suspensions listed in Appendix III. An example of a procedure to prepare and inoculate germ carriers is given in Appendix I
[11] Other methods are also common in practice, e.g. direct inoculation of the points to be investigated and examination of the points inoculated after sterilization by means of swabbing.
[12] The initial germ load should be chosen so as the medium level of dilution corresponds to the target power of decontamination of the filling machine. The level of inoculation stated here corresponds to the minimum requirements for filling machine of VDMA hygiene level V in VDMA Doc. No. 11 (2006) which is a germ reduction of 4 log cycles. Agreements on initial germ loads not matching the requirements stated in 4.2 (ii) should be stated in the test documentation as departure from this test procedure.

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v) Carrying out the sterilization program of the aseptic filling machine in the defined operating range.[13]

vi) Sterile removal of the germ carriers followed, if necessary, by separation of the sections inoculated with the three different concentrations of microorganisms under sterile conditions. Each section is placed in a test tube containing a nutrient solution[14] suitable for the test microorganism. The tubes are incubated for 3-5 days at 30 °C.[15] A yellow coloration of the broth in the tube together with formation of a thin skin on the surface indicates growth. That this is due to the inoculated test microorganism must be confirmed by means of smears.

vii) Determination of the total number of sterile germ carriers at each concentration level as a proportion of the total number of test strips introduced into the machine (= test result). If all germ carriers at concentration level 10^4 are negative the requirement set out in VDMA Doc. No. 11 (2006) for aseptic filling machines that the logarithmic count reduction be ≥ 4 is reliably fulfilled.[16]

5 Test method - Germ carrier test – Count-reduction-test

5.1 General procedure

In this test method germ carriers inoculated with the test microorganism are affixed at points in the sterile zone of the machine interior relevant to the sterilization process.[17] [18] The number of viable spores is determined before and after the application of the sterilization program of the filling machine. From the difference in microorganism counts the killing rate is calculated.

5.2 Test method

i) Prior to the test the points in the sterile zone of the machine interior relevant for sterilization and hence to be checked have to be identified. In doing so the involvement of the machine manufacturer is advisable.

ii) Provision of the required numbers of germ carriers inoculated with 10^5 microorganisms (in addition 5 germ carriers calculate the initial germ load.).[19]

iii) Introduction of the germ carriers into the clean and dry machine paying particular attention to the relevant positions for sterilization identified under i).

iv) Recording of the points occupied by germ carriers in the sterile zone of the machine interior.

[13] It is recommended that the critical process parameters (e.g. concentration of the hydrogen peroxide, temperatures) be checked prior to the test run.
[14] Bacillus subtilis, Bacillus atrophaeus and B. stearothermophilus: glucose-casein peptone solution. Composition in g/l: casein peptone 10.0; glucose 5.0; yeast extract (Oxoid CM0073) 1.0; bromocresol purple 0.04 / pH 6.9 ± 0.2.
Aspergillus niger: sabouraud 2 % glucose broth. Composition in g/l meat peptone 5.0; casein peptone 5.0; D(+) glucose 20.0; pH 5.6 ± 0.1
[15] Other appropriate combinations of time and temperatures may be agreed on and should be stated in the test documentation as departure from this test procedure where applicable.
[16] In this case the calculated logarithmic microorganism killing rate is distinctly higher than the required value of 4 log units. A quantitative statement of the microorganism reduction rate is possible when a microorganism reduction test according to section 5 of this document is carried out.
[17] Ready-to-use germ carriers could be sourced from suppliers of spore suspensions listed in Appendix III. The example of a procedure to prepare and inoculate germ carriers is given in Appendix I may be applied by analogy.
[18] Other methods are also common in practice, e.g. direct inoculation of the points to be investigated and examination of the points inoculated after sterilization by means of swabbing.
[19] The initial count shall exceed the target logarithmic reduction. If possible it should be raised to the power of 1 to target lorgarithmic reduction. Corresponding deviations from 5(ii) should be noted in the test report. The separation of the germ load on several drops may become necessary when inoculating a higher germ load.
The level of inoculation stated here corresponds to the minimum requirements for filling machines of VDMA hygiene level V in VDMA Doc. No. 11 (2006) which is a germ reduction of 4 log cycles.

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v) Carrying out the sterilization program of the aseptic filling machine in the defined operating range.[20]

vi) Sterile removal of the germ carriers.

vii) Removal of test microorganisms from the germ carrier by way of an appripriate procedure, e.g. removal with sterile Ringer's solution with 1g/l added Tween 80[21] together with ultrasonic treatment.[22] [23]

viii) Determination of the survival count for all germ carriers as well as the initial count for the five germ carriers set aside for this purpose. [24]

ix) Calculation of the logarithmic microorganism count reduction for each germ carrier according to the following formula :

$$LK_{CR} = \log[(1/5)*\Sigma AKj)] - \log[ÜK]$$

$(1/5)*\Sigma AK_j$: mean initial count
ÜK : survivor count

$j = 1, \ldots, 5$

x) The test is passed if the agreed on target logarithmic count reduction is achieved for each germ carrier affixed in iii).

6 Test report

Information to be recorded in the test report with reference to this code of practice includes:

- Name of institute conducting the test
- Brief description of the aseptic plant tested (manufacturer, exact model designation, type of packaging sterilization device, boundaries of the sterile zone in the interior of the machine)
- Settings for the machine parameters relevant to sterilization agreed with the machine manufacturer
- Required count reduction capability of the aseptic plant
- Nature and concentration of the sterilizing agent
- Date of test runs
- Precise name of the test microorganism including values from resistance testing if available
- Description of spore suspension (concentration, production specification or source of supply, age – if available)
- Total number of germ carriers introduced into the sterile zone of the machine interior
- Documentation of the points in the sterile zone of the machine interior relevant to sterilization
- Documentation of the distribution of germ carriers in the sterile zone of the machine interior
- Documentation of the actual sequence of operations in the sterilization program
- Test method applied
- Documentation of the microbiological approach (method of germ determination, culture medium, duration and temperature of incubation, recovery rate)
- Statement of **test result**
- Departures, if any, from the test specification

[20] It is recommended that the critical process parameters (e.g. concentration of the hydrogen peroxide, temperatures) be checked prior to the test run.
[21] Trading product of company Firma Merck-Schuchardt. Order-No. 8.22187.2500
[22] It is recommended the work instruction to include soaking time, validated parameter settings of the ultrasonic cleaning device, and dwell time in the ultrasonic cleaning device.
[23] To avoid a continued impact of residues of oxidative disinfectants the usage of deactivating solutions is recommended. A recipe may be found in section 5.6 of VDI 4066 Blatt 3.
[24] Only culture media and incubation conditions appropriate for the test microorganisms used should be applied. Only colonies typical in morphology should be evaluated. (cf. VDI 4066 Blatt 3 Abschnitt 5.6)

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- Test staff involved
- Signature of person responsible for the test.

7 Use of the code of practice for checking filling machines of VDMA hygiene class IV

The test specifications set out in this code of practice may also be applied by analogy to a filling machine of VDMA hygiene class IV. Minimum requirements on decontamination devices of this machine class as well as indications to select appropriate test microorganisms are stated in VDMA Doc. No. 10 (2005).

8 References

VDMA Documents Food Processing Machinery and Packaging Machinery are available as downloadable file free of charge from nuv.vdma.org if not stated otherwise.

VDI 4066 Blatt 3 Hygieneanforderungen an die Herstellung und aseptische Abfüllung von Getränken - Hinweise zu mikrobiologischen Funktionsprüfungen (Hygienic Requirements for the production and aseptic filling of beverages and dairy products – Hints to microbiological performance tests), Beuth-Verlag, 2014.

VDMA Doc. No. 3 (2nd revised edition 2008)
Food Processing Machinery and Packaging Machinery
Checklist "Quality Assurance and Maintenance" for aseptic filling machines for the food industry

VDMA Doc. No. 2 (2nd edition 2006)
Food Processing Machinery and Packaging Machinery
Hygienic Filling Machines for Liquid and Viscous Foods - Classification and Typical Fields of Application

VDMA Doc. No. 6 (2nd edition 2008)
Food Processing Machinery and Packaging Machinery
Code of Practice
Filling Machines of VDMA Hygienic Class V: Testing the Effectiveness of Packaging Sterilization Devices,

VDMA Doc. No. 10 (2005)
Food Processing Machinery and Packaging Machinery
Hygienic Filling Machines of VDMA Class IV for Liquid and Viscous Foods
Minimum Requirements and Basic Conditions for Operation in Accordance with Specification

VDMA Doc. No. 11 (2006)
Food Processing Machinery and Packaging Machinery
Aseptic Packaging Machines for the Food Industry - Minimum Requirements and Basic Conditions for the Intended Operation
supersedes VDMA 8742

VDMA Doc. No. 12 (2007)
Food Processing Machinery and Packaging Machinery
Guide to Checking the Microbiological Safety of Hygienic Filling Machines of VDMA Classes IV and V

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9 Cited standards

DIN EN ISO 14161: 2010-03
Sterilisation von Produkten für die Gesundheitsvorsorge
Biologische Indikatoren - Leitfaden für die Auswahl, Verwendung und Interpretation von Ergebnissen
Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results (ISO 14161:2009); German version EN ISO 14161:2009

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Appendix I (informative)
Preparing and inoculating the germ carriers for end-point test (Example)

Preparing the germ carriers

Strips measuring 1 x 5 cm are cut out of a suitable carrier material, e.g. an aluminum foil (0.09 mm thick). These strips are divided into 3 sections 1 cm wide and 1 section 2 cm wide. The strips are sterilized for 3 hours at 180 °C in a dry sterilizer.

The sterilized germ carriers are fixed in a sterile plastic dish by means of double-sided adhesive tape. In this case the protective strip of the adhesive tape is positioned on the reverse side of the adhesive tape in such a way that it cannot adhere completely to the bottom of the plastic dish. The adhesive strip is notched in such a way that the germ carrier together with the adhesive strip can be taken out individually.

Inoculation

Prior to use the microorganism suspension is adjusted to a (theoretical) concentration of approximately 2 x 10^7 microorganisms per ml and further dilutions (10^6 and 10^5) are made.

Inoculation is carried out in a hygienic work environment. Three concentration levels are inoculated in decreasing concentration [25]: 10^5, 10^4 and 10^3 . (Recommendation: apply concentration level 10^3 always on the lower part of the strip.) To do this 10 µl of a correspondingly concentrated spore suspension (10^7, 10^6, 10^5) are dripped onto the sections. Then the test strips are dried, after which the lid is placed on the plastic dish and stuck into place.

The microorganism counts for each dilution level in five germ carriers are determined. For this purpose the germ carriers are cut into pieces and the inoculated sections are each placed in 10 ml of diluting solution + 0.1 % Tween 80 [26]. The sections are shaken for 30 seconds on the Whirl-Mix. The colony-forming unit (CFU) in 1 ml of rinsing liquid is determined and scaled up to the CFU for the section (x 10).

Storage recommendation:

Bacillus spores: max. 4 weeks at 4-8°C in darkness
Aspergillusspores max. 2 weeks at 4-8°C in darkness

[25] When testing for a target count reduction of 4 log cycles it is recommended to set the highest inoculation level as to guarantee a sufficient survivor count for reliable counting of CFU. For a target count of 50 survivor CFU an inoculation with $10^{5.7}$ is proposed.
[26] Commercial product from Merck-Schuchardt, order No. 8.22187.2500

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Appendix II (informative)
Culture conditions for the test strains Bacillus subtilis SA 22 and Bacillus atropheus and preparation of the spore suspension (Example)

Bacillus subtilis SA 22 or Bacillus atrophaeus are first of all precultured in tryptone soya bouillon for 24 hours at 30 °C before samples of 0.1 ml each of the preculture are transferred by means of Drigalski spatula onto plate count agar added with 0.001g/l $MnSO_4$ and then are incubated for 7 days at 30 °C.

The Petri dishes in which the test microorganism has grown are each covered with a wash of 3 ml of 0.9 % sterile common salt solution after which the bacterial spore bed is carefully removed using a Drigalski spatula.[27]

The spores harvested from several Petri dishes are combined and centrifuged at 10,000 g for approximately 20 minutes. The supernatant liquid is then decanted off and the sedimented spores are resuspended in sterile 0.14 M Sørensen phosphate buffer (K2HPO4/KH2PO4, pH 7). After this centrifuging and resuspension are carried out twice in the same way until finally the spore sediment is finely suspended in sterile phosphate buffer. The spore suspension obtained in this way is heated for 20 minutes at 80 °C in order to kill off vegetative unspored cells (pasteurization). Then the suspension is centrifuged again and the spore pallets are transferred into 70% ethanol solution. The resultant spore suspension may be kept refrigerated for about 6 months or at 20°C for 8 weeks. .The spore count should range from 10^8 to 10^9/ml.

[27] Besides removing the spore bed by means of Drigalski spatula also the usage of sterile cotton swabs fit well.

Appendix III
Sources of spore suspensions

Ready to use spor suspensions of **Bacillus atropheus** (ATCC 9372, DSM 675, former Bacillus subtilis), i.a., may be sourced from:

The National Food Laboratory, Inc.
Process Research & Microbiology Division
2441 Constitution Dr
Livermore, CA 94551

BAG - Biologische Analysensystem GmbH
Amtsgerichtstraße 1-5
35423 Lich
Fax: 06404/3087

MesaLabs
12100 West 6th Ave.
Lakewood, CO 80228
12100 West 6th Avenue
Phone: 303.987.8000
Fax: 303.987.8989
http://biologicalindicators.mesalabs.com/

ifp
Institut für Produktqualität GmbH
Teltowkanalstrasse 2
12247 Berlin
http://www.produktqualitaet.com
info@produktqualitaet.com
Tel.: +49 (30)-7668600

Ready to use spore suspensions of **Bacillus subtilis SA22** (identical to NCA 72-52 and to DSM 4181) , i.a., may be sourced from (certificate of resistance on request):

Dr. Früh Control GmbH
Bettina-von-Arnim-Straße 3
61476 Kronberg

Biotecon Diagnostics
Hermannswerder Haus 17
14473 Potsdam
Tel.: +49(331)-2300200

ifp
Institut für Produktqualität GmbH
Teltowkanalstrasse 2
12247 Berlin
http://www.produktqualitaet.com
info@produktqualitaet.com
Tel.: +49 (30)-7668600

Ready to use spore suspensions of **Geobacillus stearothermophilus** NCA 1518, ATCC 7953 (identical to DSM 5934) , i.a., may be sourced from:

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BAG - Biologische Analysensystem GmbH
Amtsgerichtstraße 1-5
35423 Lich
Fax: 06404/3087

The National Food Laboratory, Inc.
Process Research & Microbiology Division
2441 Constitution Dr
Livermore, CA 94551

MesaLabs
12100 West 6th Ave.8607 Park Drive
Lakewood, CO 80228
12100 West 6th Avenue
Phone: 303.987.8000
Fax: 303.987.8989
http://biologicalindicators.mesalabs.com/

Ready to use spore suspensions of **C. sporogenes PA** (NFL-Stamm SC220 und SC 218) , i.a., may be sourced from:

The National Food Laboratory, Inc.
Process Research & Microbiology Division
2441 Constitution Dr
Livermore, CA 94551