BRITISH STANDARD

BS EN
866-7:2000

Biological systems for testing sterilizers and sterilization processes —

Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers

The European Standard EN 866-7:1999 has the status of a British Standard

ICS 11.080.10

National foreword

This British Standard is the official English language version of EN 866-7:1999.

The UK participation in its preparation was entrusted by Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors, to Subcommittee LBI/35/3, Sterilization indicators, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 8, an inside back cover and a back cover.

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Amendments issued since publication

Amd. No.	Date	Comments

This British Standard, having been prepared under the direction of the Sector Committee for Materials and Chemicals, was published under the authority of the Standards Committee and comes into effect on 15 June 2000

ISBN 0 580 34603 X

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 866-7

December 1999

ICS 11.080

English version

Biological systems for testing sterilizers and sterilization processes — Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation — Part 7: Exigences particulières pour les systèmes autonomes d'indicateurs biologiques destinés à être utilisés dans des stérilisateurs à la vapeur d'eau

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren — Teil 7: Spezielle Anforderungen an Bio-Indikator-Einheiten für den Gebrauch in Dampf-Sterilisatoren

This European Standard was approved by CEN on 19 June 1999.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN 866-7:1999 E

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 102, Sterilizers for medical purposes, the Secretariat of which is held by DIN.

EN 866 consists of the following parts under the general title *Biological systems for testing sterilizers and sterilization processes*:

— *Part 1: General requirements*;

— *Part 2: Particular systems for use in ethylene oxide sterilizers*;

— *Part 3: Particular systems for use in moist heat sterilizers*;

— *Part 4: Particular systems for use in irradiation sterilizers*;

— *Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers*;

— *Part 6: Particular systems for use in dry heat sterilizers*;

— *Part 7: Particular requirements for self-contained systems for use in moist heat sterilizers*;

— *Part 8: Particular requirements for self-contained systems for use in ethylene oxide sterilizers*.

In addition CEN/TC 102 Working Group 7 has prepared EN 867 consisting of the following parts under the general title *Non-biological systems for use in sterilizers*:

— *Part 1: General requirements*;

— *Part 2: Process indicators (Class A)*;

— *Part 3: Specification for Class B indicators for use in the Bowie and Dick Test*;

— *Part 4: Specification for indicators as an alternative to the Bowie and Dick test for the detection of steam penetration (in preparation)*;

— *Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S (in preparation)*.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Contents

Introduction

This European Standard specifies the performance requirements for self-contained biological indicator systems supplied ready for use. These systems are intended for use primarily as routine monitors. When it is intended to use self-contained biological indicators in routine monitoring, the chosen indicator system should be employed along with any other chosen indicator system during the process development and validation stages. EN 866-3 specifies the performance requirements for biological indicators supplied ready for use and for suspensions of test organisms supplied either for the preparation of biological indicators or for the inoculation of product for use in validation studies on, and routine monitoring of, moist heat sterilization processes.

The use of the indicators specified in this standard are described, inter alia, in EN 285.

The biological indicators specified in this standard are not intended for use in any process other than moist heat sterilization. The use of a biological indicator in a process other than that stated by the manufacturer can give dangerously misleading results.

The use of a biological system for testing a sterilization process does not allow necessarily the same level of sensitivity in response to inadequate levels of all the critical variables of the process.

The performance of a biological indicator can be affected by the conditions of storage prior to use, the methods of use and the techniques employed after exposure to the process. For these reasons, the recommendations of the manufacturer for storage and use should be followed and biological indicators should be transferred to the specific recovery conditions as soon as possible after exposure to the process. Biological indicators should not be used beyond any expiry date stated by the manufacturer.

Biological indicators should always be used in combination with a physical and/or chemical monitoring in demonstrating the efficacy of a sterilizing process. When a physico-chemical variable of a sterilizing process is outside its specified limits, a sterilization cycle should always be regarded as unsatisfactory, (see also EN 554) irrespective of the results obtained from the biological indicator.

1 Scope

This part of EN 866 specifies the requirements for self-contained biological indicator systems intended for use in monitoring the performance of moist heat sterilizers operating at temperatures in excess of 100 °C.

NOTE 1 EN 285 specifies the performance and test requirements for large steam sterilizers for porous loads and wrapped goods.

NOTE 2 Hermetically sealed ampules containing micro-organisms suspended in a growth medium with colour change indicator are only suitable for use in sterilizers intended to process aqueous liquids in sealed containers and are not included within this standard.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 285:1996, *Sterilization — Steam sterilizers — Large sterilizers.*

EN 866-1:1997, *Biological systems for testing sterilizers and sterilization processes — Part 1: General requirements.*

3 Definitions

For the purposes of this European Standard, the definitions given in EN 866-1 apply, together with the following.

3.1

self-contained biological indicator system

an inoculated carrier presented in a primary pack which also contains the growth medium required for recovery

3.2

survival-kill window

the extent of exposure to a sterilization process under defined conditions when there is a transition from all biological indicators showing growth (survival exposure) to no biological indicators showing growth (kill exposure)

NOTE The survival-kill window is calculated by the following formula:

survival exposure $\geq$ [$\log_{10}$ (nominal population) $-$ 2] $\times$ D value;

kill exposure $\geq$ [$\log_{10}$ (nominal population) + 4] $\times$ D value

The units for both survival and kill exposures will be the same as the units used for the D value.

4 General requirements

The requirements of EN 866-1:1997 shall apply except for **4.4**, **6.3**, clauses **8**, **9** and **10**.

5 Test organisms

The test organisms shall be spores of *Bacillus stearothermophilus* or other strains or organisms demonstrated equivalent performance as required by this European Standard.

NOTE *Bacillus stearothermophilus* NCTC 10003, ATCC 7953, DSM 494, DSM 2027, DSM 22, DSM 5934, NCTC 10007, ATCC 12980 and CIP 52.81 have been found to be suitable.

6 Population of test organisms

6.1 Replicate determinations of the viable count on the same batch of suspension used to prepare the biological indicators shall be within ±35 % of the nominal population.

6.2 The number of recoverable test organisms in each biological indicator shall be controlled during manufacture to be either within ±50 % of the nominal population stated by the manufacturer or within the minimum and maximum populations stated by the manufacturer.

6.3 Retrospective determination of the count shall be made by performing a viable count under the culture conditions on a suspension of test organisms obtained by physical removal of the test organisms from the carrier through ultrasonication, shaking with glass beads, or other appropriate, validated methods. Counts obtained shall be regarded as acceptable if they are within −50 % and +300 % of the nominal population stated by the manufacturer or the midpoint between the minimum and maximum populations stated by the manufacturer.

NOTE The method specified by the manufacturer for the removal of test organisms from the carrier should be used.

6.4 The nominal number of spores shall be not less than 1×10^5 per unit and shall be stated in increments not greater than $0{,}1 \times 10^5$.

7 Carriers

7.1 The suitability of the carrier for use in steam sterilization processes shall be demonstrated in accordance with the requirements in **6.1**, **6.2** and annex A in EN 866-1:1997.

7.2 The conditions to be used to establish compliance shall be:

— exposure to dry saturated steam at not less than the manufacturer's stated maximum;

— exposure temperature +5 °C for not less than 30 min.

If the manufacturer does not state a maximum exposure temperature, a temperature of 145 °C and an exposure time of 30 min shall be used.

NOTE These conditions have been selected to represent a realistic, but severe, challenge to the carrier whilst remaining within the practical limits of a steam sterilization process.

8 Materials of construction

8.1 The materials of which the self-contained biological indicator system is made shall withstand exposure to the sterilization process for which it is intended without distortion, melting, corrosion or other failure which would impair its utility.

Compliance shall be tested by observation of the assembled materials before and after exposure to dry saturated steam at not less than the manufacturer's stated maximum exposure temperature +5 °C for not less than 30 min and at least twice the exposure time stated by the manufacturer.

If the manufacturer does not state a maximum exposure temperature, a temperature of 145 °C and an exposure time of 30 min shall be used.

NOTE 1 The self-contained biological indicator system should be sufficiently robust to withstand transport in the secondary pack and handling at the point of use without breakage.

NOTE 2 The design of the self-contained biological indicator system should be such that:

a) it will minimize the loss of the original inoculum of test organisms during transport and handling; and

b) it is appropriate to be located in a process challenge device without impairing the function of the process challenge device.

8.2 The utility of the growth medium shall not be impaired by exposure to the sterilization process.

Compliance shall be tested by inoculation of the assembled media and subsequent incubation after exposure to dry saturated steam at not less than the manufacturer's stated maximum exposure temperature +5 °C for not less than 30 min and at least twice the exposure time stated by the manufacturer.

If the manufacturer does not state a maximum exposure temperature, a temperature of 145 °C and exposure time of 30 min shall be used.

Compliance shall be tested in accordance with the method described in annex A.

8.3 During or after the sterilization process the materials of which the self-contained biological indicator system is made shall neither retain nor release any substance to such an extent that there will be inhibition of the growth of low numbers of surviving test organisms under the culture conditions.

Compliance shall be tested in accordance with the method described in annex A.

8.4 The manufacturer shall state the maximum and minimum values of each external dimension of the self-contained biological indicator system on request.

9 Resistance

9.1 The manufacturer shall state the survival-kill window of each batch of self-contained biological indicator systems in minutes to one decimal place. The manufacturer shall state the accuracy with which the survival-kill window value was determined (e.g. $\pm$0,1 min). This accuracy shall not exceed $\pm$0,5 min.

9.2 The manufacturer shall obtain a *D* value either by the survivor curve method or by the MPN method (see annex B of EN 866-1:1997) for the spore population in the self-contained biological indicator system when exposed to dry saturated steam at (121 $\pm$ 1) °C. The *D* value so determined shall not be less than 1,5 min. This shall be determined in accordance with the method given in annex A or a method of demonstrated equivalence.

9.3 The *D* value of the spores in the self-contained biological indicator system shall be determined to not less than two other temperatures in the range 110 °C to 130 °C by either of the two methods given. These data shall be used to calculate the *z* value which shall not be less than 6 °C.

9.4 When the manufacturer specifies that the self-contained biological indicator system is for use at only one temperature, **9.3** shall not apply.

9.5 The *D* value determined in **9.2** and the nominal number of spores determined in **6.4** shall be used to calculate the survival and kill exposures in accordance with the equation in **3.2** (NOTE).

9.6 The survival exposures shall not be less than 4,5 min and not greater than 7,5 min and kill exposure shall not be less than 13,5 min and not greater than 22,5 min when determined in dry saturated steam at (121 $\pm$ 1) °C in accordance with the method in annex B.

Fifty replicates shall be used to confirm both the survival exposure and the kill exposure.

9.7 When both of the reference methods in annex B of EN 866-1:1997 have been used e.g. during third party verification, the *D* value obtained by the two methods shall be such that the higher value obtained does not exceed the lower value by more than 50 % of the lower value.

10 Packaging and labelling

Each secondary pack containing a number of self-contained biological indicators shall be accompanied by the following information:

a) name of test organism;

b) culture collection number;

c) the nominal number of test organisms per biological indicator;

d) a unique code from which the manufacturing history can be traced;

e) the number of biological indicators;

f) the recommended storage conditions;

g) the expiry date;

h) the manufacturer's name and address or other means of identification;

i) the sterilization process or range of sterilization processes for which the biological indicator is designed; this shall include the maximum temperature and exposure time which are suitable for the product;

j) directions for use; this shall include the culture conditions to be used after exposure to the sterilization process;

k) the resistance of the test organisms within the self-contained biological indicator system, expressed either as the survival-kill window at 121 °C, or at the specific process temperature (where the biological indicator is designed for only one specific process temperature other than 121 °C);

l) instructions for disposal of the inoculated carriers or biological indicators;

m) the *z* value of the test organisms within the self-contained biological indicator system over the temperature range 110 °C to 130 °C except where the biological indicator is designed for only one specific process temperature.

NOTE This requirement replaces **6.2** and **8.2** of EN 866-1:1997.

Annex A (normative)

Determination of growth inhibition by component materials, dimensional stability and the suitability of growth medium

A.1 Equipment and materials

A.1.1 *Suspension of test organisms*, of the same strain and prepared in the same manner as the organisms to be used for inoculation of carriers. The suspension shall be of known population, determined by viable count, to permit dispensing of aliquots with a population of between 10 and 100 viable organisms.

This aliquot should have a volume not exceeding 10 % of the volume of growth medium recommended by the manufacturer.

A.1.2 *Resistometer*, complying with the resistometer described in annex B.

A.1.3 *Growth medium*, of the same type and in the same volume as stated for the recovery of the biological indicator in normal use.

A.1.4 *Incubator*, set to the temperature stated for the recovery of the biological indicator in normal use.

A.2 Determination of growth inhibition of materials of construction

A.2.1 *Procedure*

A.2.1.1 Take a representative sample of 12 uninoculated carriers and divide it into six lots of two.

A.2.1.2 Determine the maximum surface area of the container (primary pack) and the growth medium container which will be in contact with the growth medium at the start of incubation (the contact area). Take sufficient pieces of material from which the primary pack and the growth medium container are constructed (the container sample) to provide a total surface area equivalent to twice the contact area. These pieces shall be of such a size that they will be completely covered by the volume of growth medium used. No allowance shall be made for the increase in contact area with the primary pack.

A.2.1.3 Place each of the two carriers of each of three of these lots in a primary container together with the container sample and then expose it to the sterilization process.

A.2.1.4 Set the operational conditions of the resistometer to the required temperature (see **7.2**), or 145 °C where no temperature was specified, for 30 min.

A.2.1.5 After exposure to the process, as soon as possible but in any case within 30 min of the end of the process, aseptically transfer an aliquot of the untreated growth medium to each container. Care shall be taken to ensure that all the container samples are covered by the growth medium.

A.2.1.6 Record the time taken to complete the transfer.

A.2.1.7 Incubate the growth medium at the stated temperature for 2 h, remove it from the incubator and inoculate it with a volume of the test organism suspension calculated to contain between 10 and 100 viable organisms. Return the inoculated media to the incubator and incubate it for the time stated by the manufacturer for the recovery of biological indicators under normal conditions of use.

A.2.1.8 For the negative control, transfer the two carriers and a container sample, not exposed to the process, to each of three containers containing the normal aliquot of growth medium, incubate them for 2 h, inoculate them with 10 to 100 test organisms, and incubate them in the same manner as described above.

A.2.1.9 For the positive control, incubate three containers, each containing the normal aliquot of growth medium but containing no carriers or container samples, for 2 h inoculate them with 10 to 100 test organisms, and incubate them for the stated recovery period in the same manner as described above.

A.2.1.10 At the end of the stated recovery period remove all nine containers from the incubator and examine them for viable organisms in accordance with the manufacturers instructions.

A.2.1.11 Report the results as “growth” or “no growth” of the test organism.

A.2.2 *Interpretation of results*

A.2.2.1 If “no growth” occurs in one or more of the positive controls the test procedure shall not be regarded as valid.

NOTE No growth in the positive control can be indicative of failure to control the population of the test organism inoculum, or, of inappropriate recovery conditions (growth medium, temperature etc.).

A.2.2.2 If “no growth” occurs in one or more of the negative controls the test procedure shall not be regarded as valid.

NOTE No growth in the negative control, but growth in the positive control can indicate that the material of which the carrier is made is itself inhibitory to the growth of the test organism.

A.2.2.3 If “no growth” occurs in one or more of the three tests on carriers exposed to the process the carrier shall not be regarded as suitable for the manufacture of inoculated carriers or biological indicators.

NOTE No growth can be caused either by leaching of materials from the carrier by the sterilant or by degradative changes in the material of the carrier during the process.

A.3 Dimensional and growth medium stability

A.3.1 Expose five self-contained biological indicator systems (with no test organisms present) from each of three batches in a resistometer as described in annex B. Set the operational conditions of the resistometer to the required temperature (see **7.2**), or 145 °C where no temperature was specified, for 30 min.

A.3.2 At the end of the exposure period measure and visually examine each sample to determine whether the external dimensions remain within the tolerances specified by the manufacturer (see **6.3** of EN 866-1:1997) and that no distortion or other failure which could compromise the utility of the device has occurred.

A.3.3 Following this examination, release the growth medium into the container in the manner defined by the manufacturer and then inoculate it with a volume of the test organism suspension calculated to contain between 10 and 100 viable organisms. Transfer the inoculated media to the incubator and incubate it for the time stated by the manufacturer for the recovery of biological indicators under normal conditions of use.

A.3.4 After incubation examine all five biological indicators for signs of growth by the method described by the manufacturer.

If any one of the five samples in each batch show no growth this shall be regarded as a failure in growth medium stability for that batch.

If there are samples from two or more batches showing no growth this shall be regarded as a failure in growth medium stability.

Annex B (normative)

Determination of resistance to steam sterilization

B.1 Apparatus: Steam biological indicator resistometer

B.1.1 The equipment shall be capable of maintaining the conditions given in Table B.1 within the limits given for exposure periods between 5 s and 180 min to an accuracy of $\pm$1 s.

Table B.1 — Conditions

Variable	Range	Accuracy
Temperature	110 °C to 145 °C*)	$\pm$0,5 K
Pressure	140 kPa to 425 kPa*)	$\pm$2,5 kPa
Vacuum range	$\leq$ 0,05 kPa to 100 kPa	$\pm$0,02 kPa

*) or such other maximum operating temperature and pressure as can be necessary to conduct the test described in **7.1**.

B.1.2 The equipment shall be provided with means to evacuate the reaction chamber to less than 5 kPa within 2 min, to permit adequate air removal prior to admission of steam.

When it is necessary to remove further quantities of air this may be achieved by alternate steam admission and evacuation to a temperature maximum of 80 °C and this forced air removal stage shall be completed within 5 min.

B.1.3 Air admitted at the end of the cycle shall be filtered through a filter having the ability to remove not less than 99,9 % of 0,5 μm particles.

B.1.4 The chamber and door shall be provided with means to maintain the temperature of the inner surfaces of the chamber at the required operating temperature.

B.1.5 The chamber shall be supplied with saturated steam from a source external to the chamber. The steam supply shall meet the requirements given in **13.3.2**, **13.3.3**, **13.3.4** of EN 285:1996.

NOTE These subclauses in EN 285 specify requirements for steam quality and define acceptable limits for entrained moisture, superheat and non-condensible gases.

B.1.6 The equipment shall be capable of automatic operation and shall be provided with a system for recording temperature and pressure within the chamber which is independent of the control function. The limits of error on the recording equipment, at the operational temperature and pressure, shall not exceed 50 % of the tolerance allowed for each control variable.

B.1.7 The time for the temperature to rise within the resistometer chamber shall not exceed 10 s.

B.1.8 At the end of the exposure period the temperature in the resistometer chamber shall be reduced to 100 °C or less in a period not exceeding 10 s, and the chamber shall return to ambient pressure in not more than 5 s.

B.1.9 The resistometer shall be equipped with a sample holder designed to ensure that the items under tests are not subjected to excessive condensate or superheat. (Appropriate limits are given in EN 285 in the requirements for steam quality).

B.2 Procedure

B.2.1 Load the biological indicators onto a suitable sample holder.

B.2.2 Pre-heat the resistometer chamber to the required operating temperature e.g. (121 $\pm$ 1) °C.

B.2.3 Place the loaded sample holder in the chamber, close the chamber and leave for the time previously determined as necessary to allow the temperature to stabilize.

B.2.4 Carry out the following sequence of operations under automatic control:

a) evacuate the chamber to (4,5 ± 0,5) kPa within 2 min and complete any forced air removal stage within 5 min;

b) admit steam to the chamber to obtain the required temperature and pressure;

c) for the 0 min exposure time no steam should be admitted;

d) maintain these conditions for the required exposure period;

e) at the end of the exposure period, evacuate the chamber to (4,5 ± 0,5) kPa, attaining 100 kPa within 5 s, and then admit filtered air, or an inert gas such as nitrogen, to ambient pressure.

B.2.5 At the end of the above cycle remove the sample holder from the chamber.

B.2.6 Within 2 h, or as otherwise specified by the manufacturer, carry out any manipulations required to bring the test organisms into contact with the recovery medium and incubate in accordance with the manufacturer's instructions.

B.3 Verification of survival-kill window

B.3.1 Not less than 50 indicators exposed to the specified conditions (see **9.2**) for not more than the time calculated from the *D* value for survival of all biological indicators (see **3.2** and **9.3**). All of the indicators shall show growth when recovered according to the manufacturer's instructions.

B.3.2 Not less than 50 indicators exposed to the specified conditions (see **9.2**) for not less than the time calculated from the *D* value for the kill of all biological indicators (see **3.2** and **9.3**). None of the indicators shall show growth when recovered according to the manufacturer's instructions.

Bibliography

EN 554, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat.*

EN 866-3, *Biological systems for testing sterilizers and sterilization processes — Part 3: Particular systems for use in moist heat sterilizers.*

EN 1174-2, *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 2: Guidance.*

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