

Sterilizing and disinfecting equipment for medical products —

Part 1: Specification for general requirements

UDC 615.478.73.74:006.3/8

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The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/14, upon which the following bodies were represented:

- Associated Offices Technical Committee
- Association of British Sterilizer Manufacturers
- Association of Clinical Pathologists
- Association of National Health Service Supplies Officers
- British Dental Trade Association
- British Health-Care Trade and Industry Council
- British Surgical Trades Association Incorporated
- Central Sterilising Club
- Department of Health
- Guild of Hospital Pharmacists
- Health and Safety Executive
- Infection Control Nurses' Association
- Institute of Hospital Engineering
- Institute of Purchasing and Supply
- Institute of Sterile Services Management
- Joint Committee of Professional Nursing, Midwifery and Health Visiting Associations (England)
- Medical Sterile Products Association
- National Blood Transfusion Service
- Public Health Laboratory Service
- Regional Hospital Boards Engineers' Association
- Royal College of Pathologists
- Royal Pharmaceutical Society of Great Britain
- Scottish Home and Health Department
- Stainless Steel Fabricators' Association of Great Britain

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 29 June 1990

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First published January 1966
Second edition June 1990

The following BSI references relate to the work on this standard:
Committee reference HCC/14
Draft for comment 85/53987 DC

ISBN 0 580 17940 0

Amendments issued since publication

Amd. No.	Date of issue	Comments

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Foreword

This Part of BS 3970 has been prepared under the direction of the Health Care Standards Policy Committee. It is published simultaneously with BS 3970-3 and, together, they supersede BS 3970-1:1966 which is withdrawn.

Parts 1 and 2 of the first edition of BS 3970 were both published in 1966 and covered two specific types of sterilizer. However, in this revision the structure of BS 3970 has been changed so that general requirements applicable to all sterilizers and disinfectors are now given in this Part. Those requirements that are not common to most types of sterilizer are specified in subsequent Parts of BS 3970. These Parts, giving particular requirements, should be read in conjunction with BS 3970-1, which they supplement or modify. The titles of these Parts are expected to be as follows:

- *Part 3: Specification for steam sterilizers for wrapped goods and porous loads;*
- *Part 4: Specification for transportable steam sterilizers for unwrapped instruments and utensils¹⁾;*
- *Part 5: Specification for low-temperature steam disinfectors¹⁾;*
- *Part A: Specification for steam sterilizers for fluids in sealed rigid containers¹⁾;*
- *Part B: Specification for steam sterilizers for fluids in unsealed vented containers¹⁾;*
- *Part C: Specification for steam sterilizers for fluids in sealed non-rigid containers¹⁾;*
- *Part D: Specification for sterilizers using low-temperature steam with formaldehyde¹⁾;*
- *Part E: Specification for sterilizers using ethylene oxide or ethylene oxide mixtures¹⁾;*
- *Part F: Specification for steam sterilizers for unwrapped utensils, instruments and holloware¹⁾.*

This Part and BS 3970-A which is to be published shortly will together supersede BS 3970-2:1966.

BS 3970-5:1968 “Electrically heated steam generators for use with hospital sterilizers” no longer forms part of BS 3970 and has been withdrawn.

Other British Standards related to sterilizing and disinfecting equipment include the following:

- BS 2646, *Autoclaves for sterilization in laboratories.*
- BS 2745, *Specification for bed pan and urine bottle washers.*
- BS 2904, *Specification for hospital sterilizers (boiling water type).*
- BS 3281, *Rectangular metal boxes for use in high vacuum steam sterilizers.*
- BS 3421, *Electrically heated sterilizing ovens.*
- BS 5076, *Hospital storage cabinets for bottled fluids.*
- BS 6254, *Specification for creped sterilization paper for medical use.*
- BS 6255, *Specification for plain sterilization paper for medical use.*
- BS 6256, *Specification for paper for steam sterilization paper bags for medical use.*
- BS 6257, *Specification for paper bags for steam sterilization for medical use.*
- BS 6871, *Specification for heat-sealable pouches and tube material converted from transparent plastics film and paper for steam sterilization for medical use.*

¹⁾ In preparation; each Part will be allocated a number in its respective order of publication.

The United Kingdom statutory requirements given in Section 6 of the Health and Safety at Work etc. Act 1974 are applicable to sterilizers and the practice of sterilization. That Section describes the general duties of manufacturers, etc., regarding articles and substances for use at work and covers the design, manufacture, import and supply of any articles for use at work. However, for sterilizers that are classed as steam boilers or steam receivers, there are additional legal requirements which are set out in Sections 32 to 35 of the Factories Act, 1961.

In addition, Health Technical Memorandum (HTM) 10 "Sterilizers", published by the Department of Health and Social Security, contains further information on installation and maintenance as well as on the subsequent use of sterilizers.

BS 3970 has been prepared on the basis that every individual sterilizer or disinfectant will be subjected to functional performance tests. Unless otherwise stated in this standard, compliance with the performance requirements are checked by visual inspection or direct measurement. Reference is also made to the Electrical Safety Code for Hospital Laboratory Equipment²⁾ (ESCHLE), since sterilizers are required to comply with some of its provisions.

The test methods and requirements of this British Standard are equally applicable for assessing the functional performance of the sterilizer throughout its life.

It is essential that a sterilizer is used only for sterilizing the type of goods for which it is designed. It is normally undesirable for a sterilizer to be designed to process more than one type of goods. The choice of type of sterilizer, operating cycle or quality of the services provided may be inappropriate for a particular load although means cannot necessarily be provided to detect an incorrect choice or a misuse.

For goods infected with dangerous pathogens in Hazard Group 4 (as given in the Report of the DHSS Advisory Committee on Dangerous Pathogens³⁾), additional precautions are needed in the design of the drainage and ventilation systems to protect both users and the environment.

Attainment of sterilization conditions should be assured by validation procedures. For steam sterilization, the attainment of certain specified sterilizing conditions is indicated by physical measurements because sufficient data exist to substantiate this approach. This is not the case for sterilizers using gaseous agents where other validation procedures are necessary.

This Part of BS 3970 requires the pressure vessel to be constructed to comply either with BS 5500 or with the relevant requirements of this standard. If the latter, the manufacturer or his agent is required to satisfy the Inspecting Authority that the sterilizer is safe in respect of its use as a pressure vessel (see 5.6). The vessel may be certified by the manufacturer or his agent provided that the vessel is manufactured in accordance with the principles described in BS 5750-1.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification for product conformity with this British Standard, based on testing and continuing surveillance which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

²⁾ Published as Health Equipment Information (HEI) No. 158 by the UK Departments of Health.

³⁾ The Hazard Groups are listed in "Categorization of pathogens according to hazard and categories of containment", the Advisory Committee on Dangerous Pathogens, HMSO, 1984. Attention is also drawn to the requirements of the Health and Safety (Dangerous Pathogens) Regulations 1981 which apply to those pathogens listed in Schedule 1 of the Regulations.

Enquiries as to the availability of third party certification schemes may be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

Alternatively, users of this British Standard may wish to consider the desirability of assessment and registration of a supplier's quality systems against the appropriate Part of BS 5750 by a third party certification body.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, pages 1 to 42, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This Part of BS 3970 specifies general requirements for sterilizers, including disinfectors, comprising a pressure-tight vessel capable of operating up to a design pressure of 6.0 bar⁴⁾. These sterilizers and disinfectors are intended to be used for medical, dental, pharmaceutical, veterinary and industrial or related purposes.

NOTE 1 Not all sterilizer vessels specified by BS 3970 are required to withstand a design pressure of 6.0 bar. A lower design pressure appropriate to the particular sterilizer and the load to be processed may be specified in relevant subsequent Parts of BS 3970.

The requirements of this Part of BS 3970 apply to all sterilizers and disinfectors specified in subsequent Parts of BS 3970, except insofar as they may be modified or added to by a subsequent Part, in which case the requirements of the particular Part will apply.

Appendix A indicates the additional information that should be provided by the purchaser to the manufacturer.

NOTE 2 Purchasers ordering to this standard are advised to specify in their purchasing contract that the sterilizer manufacturer operate a quality system in accordance with the principles described in BS 5750-1. (Guidance on the application of BS 5750-1 is given in BS 5750-4.) In addition, the manufacturer is advised to check that each supplier of accessories, fittings and other materials similarly operates a quality system in accordance with the principles described in BS 5750.

NOTE 3 It is essential that a sterilizer should be used only for sterilizing the type of goods for which it is designed (see foreword). In selecting the appropriate sterilizer, reference should be made to the list of Parts of BS 3970 given in the foreword.

NOTE 4 The titles of the publications referred to in this standard are listed on page 41.

2 Definitions

For the purposes of this Part of BS 3970 the following definitions apply.

NOTE The terms that have been defined in this Part of BS 3970 are identified in the index.

2.1 sterilizer

equipment that incorporates a pressure vessel with a tightly-fitting door and which is used for the sterilization (2.3) of a load (2.5)

2.2 disinfector

equipment incorporating a pressure vessel used for disinfection (2.4) of a load (2.5)

NOTE In this standard, the term sterilizer is generally used to encompass disinfector unless the latter is specifically stated.

2.3 sterilization

the process used to render a load (2.5) free from viable micro-organisms

2.4 disinfection

the process used to reduce the number of viable micro-organisms in a load (2.5) but which may not necessarily inactivate some viruses and bacterial spores

2.5 load

collectively, all the goods, equipment and materials that are put into a sterilizer (2.1) or disinfector (2.2) at any one time for the purpose of processing it by an operating cycle (2.26)

NOTE In order to manipulate the load, various devices (such as trucks, carriages and shelving) may be necessary to carry the load. These devices (see clause 16) are usually provided by the manufacturer of the sterilizer.

2.6 load module

a rectangular container of height 300 mm, breadth 300 mm and depth 600 mm, commonly used to hold the load (2.5)

2.7 vessel

collectively, the chamber (2.9), jacket (if fitted), doors and components that are in permanently open connection with the chamber

NOTE The vessel does not include steam generators, pipework and fittings from which it can be isolated.

2.8 small sterilizer

a sterilizer (2.1) of such a size that it is unable to accommodate a single load module (2.6)

2.9 chamber

that part of the vessel (2.7) in which the load is placed

2.10 chamber height and breadth

for a rectangular chamber, the minimum internal dimensions of the chamber, measured along an axis which passes through the geometric centre of the chamber or door opening (whichever is the smaller) but excluding corner radii

⁴⁾ 1 bar = 10⁵ N/m² = 10⁵ Pa. (See also note to 13.2.2.)

2.11
chamber diameter

for a cylindrical chamber, the minimum internal diameter (excluding functional protrusions) of the chamber or of the door opening, whichever is the smaller

2.12
chamber depth

the minimum internal dimension of the chamber, measured in accordance with one of the following:

- a) from the internal surface of the door to either:
 - 1) the inner surface of the end-plate, if its surface is flat; or
 - 2) the beginning of the curve of the end-plate if its surface is concave;
- b) if the chamber has a planar door at each end, between the internal surfaces of the two doors;
- c) if the internal surfaces of the doors are convex to the chamber, from the crown of the convex portion of the doors or any projection attached to it.

2.13
usable chamber space

the maximum volume of load which the chamber (2.9) is designed to accommodate

2.14
double-ended sterilizer

a sterilizer (2.1) in which there is a door (see 2.15 and 2.16) at each end of the chamber. (See note to 2.16.)

2.15
loading door

the door in a double-ended sterilizer (2.14) through which the load is put into the chamber prior to sterilization. (See note to 2.16.)

2.16
unloading door

the door in a double-ended sterilizer (2.14) which is opened only at the end of a successful operating cycle (2.26) to withdraw the load from the chamber

NOTE In a sterilizer (2.1) with only one door, this door acts as both loading door and unloading door.

2.17
gauge pressure

pressure measured from atmospheric pressure

2.18
absolute pressure

pressure measured from absolute vacuum

2.19
design pressure

the maximum internal gauge pressure which the vessel is designed to withstand and which is used in the design calculations

2.20
maximum permissible working pressure

the maximum gauge pressure at which the vessel may be operated

NOTE 1 The maximum permissible working pressure is stipulated in the certificate of compliance issued by the manufacturer (see 5.7). It is to be not greater than the design pressure (2.20) and may be varied during the working life of the vessel.

NOTE 2 In practice the maximum permissible working pressure, the design pressure and the pressure at which the safety valve should lift are the same.

2.21
operating pressure

the gauge pressure at which the vessel is operated during normal use

NOTE The operating pressure may be indicated in subsequent Parts of BS 3970.

2.22
commissioning

the inspection and testing of a sterilizer or disinfectant (usually newly-installed) to confirm that it complies with a specification in respect of the design criteria and the performance tests (2.23) and to confirm that the services have been correctly connected and all necessary interlocks have been fitted and proved to be functional

2.23
performance tests

the tests, described in subsequent Parts of BS 3970, which are to be carried out at the time of commissioning or subsequently during the life of the sterilizer or disinfectant or, possibly, at the time of its manufacture

2.24
validation

the specified procedures which provide evidence that the sterilization process is capable of producing an acceptable and repeatable assurance of sterility. (See foreword.)

2.25
automatic controller

a device that, in response to pre-determined cycle variables, operates the sterilizer sequentially through the required stages of the process

2.26
operating cycle

the complete set of stages of the process that is carried out in the sequence as regulated by the automatic controller (2.25)

2.27
cycle variables

the physical properties, e.g. time, temperature and pressure, that influence the efficacy of the sterilization process

2.28 override

the system by which the operating cycle (2.26) can be interrupted or modified as necessary

2.29 monitoring

a function of the automatic controller (2.25) to check the attainment or otherwise of the pre-set cycle variables (2.27) essential to the efficacy of the operating cycle (2.26)

2.30 fault

the recognition by the automatic controller (2.25) that the pre-set cycle variables for the operating cycle have not been attained and that the sterilization (2.3) has been jeopardized

2.31 fail-safe

an attribute of sterilizer design whereby failure of any component or its associated services does not create a safety hazard

2.32 safety hazard

a potentially detrimental effect on persons or the surroundings arising directly from either the sterilizer or its load

2.33 cycle complete

recognition by the automatic controller that the pre-set values for the cycle variables, necessary for a successful operating cycle, have been attained

2.34 inspecting authority

the independent body or association appointed by the manufacturer or the purchaser to carry out the duties required by BS 5500 and by this standard

2.35 active chamber discharge

the controlled flow of air or of air and condensate from the chamber, such that the temperature of the discharge is at the temperature of the chamber

2.36 active drain

an active chamber discharge which is situated at the lowest part of the chamber

3 Testing for compliance

Unless otherwise specified, compliance with the requirements specified in this standard shall be checked by visual inspection and, where practicable, by direct measurement.

4 Size, shape and designation of the chamber

4.1 The chamber volume shall not exceed 170 % of the usable chamber space.

Compliance shall be checked by direct measurement of the principal dimensions, i.e. chamber depth (2.10), and either chamber diameter (2.11) or chamber height and breadth (2.9).

4.2 The shape of the usable chamber space shall be designated as follows:

- type CH : cylindrical horizontal;
- type CV : cylindrical vertical;
- type R : rectangular;
- type S : other.

For type S, the shape shall be indicated in the accompanying documents.

4.3 The size of the usable chamber space shall be designated as follows, by reference to the principal dimensions, measured in millimetres.

a) For types CH and CV: 000/000

in which

- 1) the first three digits give the diameter of the usable chamber space; and
- 2) the last three digits give the depth of the usable chamber space.

b) For type R: 000/000/000

in which

- 1) the first three digits give the height of the usable chamber space;
- 2) the next three digits give the breadth; and
- 3) the final three digits give the depth.

c) For type S: 000/000

in which

- 1) the first three digits give the minimum inscribed diameter; and
- 2) the last three digits give the depth of the usable chamber space.

d) If the depth exceeds 1 000 mm, then four digits shall be used, without a decimal point.

Examples. Examples of the system of designating shape and size are as follows:

type CH/125/254⁵⁾;

type R/914/660/990.

That is the shape and size designations may be combined.

⁵⁾ A type with the dimensions designated by CH/125/254 would be classed as a small sterilizer (see 2.8).

5 Vessel and its components

5.1 General

NOTE In the selection of the materials of construction for pressure parts and their integral attachments, account should be taken of the suitability of the material with regard to its fabrication and to the conditions under which they will eventually operate. Due attention should be paid to the effects of galvanic attack and differential expansion when dissimilar metals are used in contact.

5.1.1 Vessels complying with BS 5500. Except for the vessels specified in **5.1.2**, vessels shall comply with one of the following:

- a) construction category 3 of BS 5500;
- b) for vessels constructed of aluminium and aluminium alloys, construction category 2 of BS 5500.

NOTE The choice of the materials of construction of the chamber (see BS 5500) should be stated by the purchaser (see also Appendix A).

5.1.2 Vessels not complying with BS 5500. Except for the vessels specified in **5.1.1**, vessels shall comply with one of the following:

- a) for vessels constructed of copper and copper alloys, the design strengths and the design, manufacturing and inspection procedures given in Appendix B;
- b) BS 1746, including vessels which were constructed initially to comply with BS 1746 but which have subsequently been modified by the sterilizer manufacturer following consultation with and the written agreement of the vessel manufacturer (see note): (See also **8.2.2**.)

NOTE BS 1746 specifies requirements for domestic pressure cookers and is intended to apply to vessels not exceeding 10 L in volume and with a nominal operating pressure not exceeding 140 kPa gauge. For the purposes of BS 3970, these limitations are not applicable.

- c) for vessels of one-piece construction which do not comply with BS 1746, the design procedure of section three of BS 5500:1988 using the materials and design strengths specified in section two of BS 5500:1988 (see also **8.3**);

NOTE Vessels of one-piece construction are generally used for small sterilizers.

- d) for rectangular vessels (see **4.2** and **4.3**), the design procedure of Appendix C of this Part of BS 3970 and the construction specified in **5.1.1** or item a) of **5.1.2** of this Part of BS 3970, as appropriate.

5.2 Clad materials

For all vessels, if clad material is used:

- a) the cladding shall have a thickness of not less than 8 % of the total thickness of the composite material;
- b) the thickness of the cladding shall be ignored when calculating the design strength;

- c) the presence of the cladding shall not weaken the welding of the base material.

NOTE The cladding material should be of metal and provide corrosion resistance to the environment to be expected within the chamber. Selection of the cladding material should take account of the note to **5.1**. The cladding material need not comply with section two of BS 5500:1988.

5.3 Fatigue life

The vessel shall be designed to withstand the number of operating cycles calculated from the equation:

$$\text{Number of operating cycles} = \frac{25\,000}{t}$$

where t is the minimum operating cycle time (in h) specified in the relevant Part of BS 3970.

NOTE Guidance in the design of type CH and CV vessels that are subject to fatigue is given in Appendix C of BS 5500:1988 and for rectangular vessels, type R, in Appendix C of this Part of BS 3970.

5.4 Thermocouple entry connections

There shall be at least two thermocouple entry connections fitted to the vessel. One entry connection shall be fitted on each side of the chamber within 150 mm of the internal face of the door and at least 100 mm from any internal or external obstructions.

Each thermocouple entry connection shall terminate in a male thread complying with size G 1 A of BS 2779 and shall have a minimum bore diameter of 8 mm. If a connection is not used, it shall be closed with a sealing cap incorporating an O-ring seal.

NOTE During manufacture of the vessel, it may be convenient to provide female thermocouple entry connections. Adaptors can then be fitted at installation of the sterilizer to provide the specified male connection.

5.5 Components

5.5.1 Components, including ancillary vessels, that are connected to the vessel and that are required to contain the design pressure of the vessel, shall comply with **5.1**.

5.5.2 Air receivers, pipes and pipe fittings shall comply with the appropriate standard listed in Table 1.

Table 1 — British Standards for receivers, pipes and pipe fittings

Air receivers	Pipes	Pipe fittings
BS 5169	BS 806 BS 1306 BS 1387 BS 2871-2 BS 3059-2 BS 3601 BS 3604 BS 3605 BS 6362	BS 1740-1 BS 1965-1 BS 4504-1 and BS 4504-2 BS 4865-1 and BS 4865-2 BS 5222-1 and BS 5222-2

5.6 Manufacturer's inspection

5.6.1 If the vessel is not constructed in accordance with BS 5500 (see note), then an inspection of the vessel shall be carried out by or on behalf of the manufacturer or his agent in order to ensure that:

- a) the vessel has been manufactured in accordance with BS 3970 within a quality system which has been approved by the Inspecting Authority;

NOTE A quality system operated in accordance with BS 5750-1 would satisfy this requirement (see also foreword).

- b) when welding procedures are used to construct or modify the vessel, the inspection shall be as specified in 5.1 or Table 5A.8.10 of BS 5500:1988, as appropriate; and

- c) the vessel is marked as detailed in 18.1.1.

The manufacturer shall advise the purchaser of the Inspecting Authority referred to in item a).

NOTE If the vessel is constructed to comply with BS 5500, its construction, inspection and the issue of a certificate of compliance are specified in that standard.

5.6.2 For serially-produced vessels with a chamber of one-piece construction, not less than two vessels from each batch or two vessels from each shift, whichever is the lesser, shall be inspected.

5.7 Certificate of compliance

On completion and satisfactory inspection of the vessel, the manufacturer shall issue a certificate of compliance in accordance with either a) or b).

- a) For vessels constructed to comply with BS 5500, the certificate of compliance shall be as specified in 1.4.4 of BS 5500:1988 (see 5.1 of this Part of BS 3970).

- b) For vessels not constructed to comply with BS 5500, the certificate of compliance shall be as shown in Figure 1. The manufacturer shall certify that the vessel has been designed, constructed and tested in accordance with this Part of BS 3970. The certificate shall be countersigned, if appropriate (see 5.6), by the Inspecting Authority as evidence that it has been so designed, constructed and tested.

6 Doors and their controls

6.1 Doors and their interlocks

6.1.1 All interfaces between a door and the chamber shall be fitted with a door-seal. For the purposes of cleaning and replacing the door-seal, provision shall be made to permit access to the contact surfaces.

6.1.2 All door interlock systems shall be fail-safe (see item a) of 6.1.6) and shall incorporate two or more independent interlocks such that in the event of failure of any one service or any one interlock, at least one of the interlocks will continue to function.

Compliance is checked:

- a) by inspection of the interlocks; and
- b) after disabling each service and each interlock in turn, by establishing that the requirements of 6.1.5 and 6.1.6 are satisfied.

6.1.3 Provision shall be made to permit any door to be closed without locking so that it may be opened subsequently without a test or operating cycle having been initiated.

6.1.4 The operating cycle shall not be capable of being started until the doors are closed and locked. The doors shall be capable of being unlocked and opened only after completion of an operating cycle (see also 6.1.7).

6.1.5 Closing interlocks shall be provided to ensure that steam cannot enter nor be generated in the chamber and that compressed air or other gases cannot enter the chamber until the door-locking members are engaged to the extent specified by the manufacturer at the time of supply [see 17.1 f)].

6.1.6 Opening interlocks shall be provided to ensure:

- a) that the door-locking mechanism cannot be released until the gauge pressure in the chamber is within 200 mbar of atmospheric pressure; and
- b) that the door cannot be opened until the chamber has been effectively vented to atmospheric pressure.

6.1.7 If a fault (see clause 14) occurs during an operating cycle, access to the load shall necessitate the use of a special key, code or tool (see also 13.7.5 and 13.8.1).

6.2 Control of power-operated doors

6.2.1 If, during an operating cycle, the sterilizer becomes isolated from any of the services powering the door movement, the position of the door shall remain unchanged. If the services powering the door fail whilst the door is opening or closing this failure shall not create a safety hazard. The restoration of services powering the door after a failure shall not create a safety hazard.

Certificate of compliance with BS 3970 : Part ...*				
(To be completed for each pressure vessel.)				
<i>Sterilizer type</i>				
<i>Vessel description</i>	Boiler/Receiver			
	Approximate internal dimensions			
	Drawing numbers†			
				
				
<i>Manufacture</i>	Year of manufacture			
	Name of manufacturer			
	Manufacturer's serial no. or cipher (see note 1)			
	Name of Design Organization (if not above manufacturer)			
	Name of Inspecting Authority approving the design			
	Name of Inspecting Authority verifying the QC system			
	Design pressure (in bar)			
	Design temperature (in °C)			
<i>Post-weld heat treatment</i>	Component temperature °C Holding time h			
	Annealed/Stress relieved/Normalized (delete where inapplicable)			
<i>Hydraulic pressure test</i>	Location	Test pressure bar	Test medium and temperature °C	Date
				
				
We hereby certify that the design of this vessel complies with BS 3970 : Part * and has been approved by				
(Inspecting Authority)				
Reference of Inspecting Authority, approval				
For manufacturer		Date:		
Position:		Name of company:		
We hereby certify that this vessel has been constructed and tested in compliance with BS 3970 : Part *				
For manufacturer		Date:		
Position:		Name of company:		
* Insert Part number.				
† The drawings are to indicate the materials of construction.				
NOTE The suffix "XX" should be added to the serial number of each vessel for which any deviations or concessions have been authorized.				

Figure 1 — Certificate of compliance form

6.2.2 Provision shall be made to enable the door(s) to be opened manually if the sterilizer becomes isolated from any of the services powering the door mechanism. This provision shall not otherwise circumvent any safety devices.

6.2.3 A device, e.g. a safety edge, or devices shall be fitted to the doors in order to sense the force of an obstruction to the movement of a door when closing. The device on sensing the force shall cause the movement of the door to be reversed. The force required to actuate the device shall not exceed 15 N. The subsequent closing movement of the door, after the device has sensed an obstruction, shall not impose a force greater than 150 N on the obstruction before the reversal of the door.

NOTE 1 An alarm may operate if the device is actuated.

NOTE 2 If the mechanism operating the door cannot impose a force greater than 150 N on an obstruction and if the closure of the door cannot cause a shearing action between the door and other parts of the sterilizer which are accessible to the operator, no device is required.

NOTE 3 If, when opening, the door or its mechanism protrudes into the plant room or similar working area, that section of the door and its mechanism should be so designed and constructed that no safety hazard arises from their movement. If this cannot be achieved, guard rails and similar safeguards as described in BS 5304 should be used.

6.2.4 A device shall be fitted so that the door can be secured in an open position by means of a lock, the key of which can be removed and retained by any person entering the chamber.

6.3 Control of manually-operated doors

6.3.1 If the door is locked by means of a screwed spindle, it shall be fitted with a heat-insulated handwheel or handles. The screwed thread of the spindle shall comply with BS 5346.

The nut shall have a minimum axial length that is not less than 40 % of the diameter of the spindle.

Provision shall be made for the inspection and lubrication of the entire length of the thread of the spindle.

6.3.2 If radial locking arms are fitted, they shall be enclosed by a cover which shall be removable and replaceable irrespective of the position of the locking arms. When removed, the cover shall permit inspection and maintenance of the locking mechanism.

6.3.3 Explicit instructions shall be displayed on the fascia panel adjacent to the door or on the operator's control panel, describing the manual action required to lock the door.

In addition, if the unlocking procedure is not the reverse of the locking procedure, there shall be a description of the manual action required to unlock the door. This description shall be clearly displayed either on the door or on its handle or handwheel.

6.3.4 The door mechanism shall be such that the force to be applied by an operator in order to either lock or unlock the door does not exceed 250 N.

6.4 Control of doors of a double-ended sterilizer

6.4.1 The control initiating the automatic cycle shall be at one end of the chamber only.

When the loading door is closed and locked it shall not be possible to open the unloading door until the sterilizer has completed a successful operating cycle, i.e. without showing a fault (see clause 14).

If a fault occurs, it shall be possible to open only the loading door (see 6.1.7).

It shall not be possible:

- a) for an operator to open or close a door at the end of the chamber remote from the operator; nor
- b) for the two doors to be open simultaneously.

6.4.2 A visual display shall be provided at both ends of the sterilizer to indicate when both doors are closed and locked.

6.4.3 The indication "CYCLE COMPLETE" or an equivalent indication [see 13.1.6 f)] shall be cancelled when the unloading door is unlocked, and the loading door shall remain locked until the unloading door has been locked again.

7 Control valves and over-pressure protection devices

7.1 General

No valve connected to the chamber:

- a) shall be fitted where the system temperatures and pressures can exceed 80 % of the maximum stated by the manufacturer of the valve; nor
- b) when supplied, shall permit a leak greater than 5 % of the total leakage stated by the sterilizer manufacturer for each stage of the operating cycle [see 17.1 g)].

NOTE Gas leaks should be referred to a standard temperature and pressure of 273 K and 1 000 mbar, respectively.

Replacement of the valves connected to the chamber shall not require the removal of any connecting pipes.

7.2 Over-pressure protection devices

7.2.1 If it is possible for the pressure in the vessel, during its intended use, to become greater than or less than atmospheric pressure, the vessel shall be fitted with an over-pressure protection device complying with either BS 2915, for bursting discs, or BS 6759-1, for safety valves.

NOTE 1 If two or more vessels are connected together without any interconnecting valve, a single over-pressure protection device may be fitted.

NOTE 2 If the source of pressure or heat is external to the vessel and is such that the maximum permissible working pressure cannot be exceeded, a protection device need not be fitted.

7.2.2 The over-pressure protection device shall be set to operate at a pressure not higher than the maximum permissible working pressure. It shall be of a size that, in the event of failure to control the pressure, will ensure the pressure within the vessel does not exceed the maximum permissible working pressure by more than 10 %.

Compliance is checked by testing the vessel at the maximum acceptable pressure stated by the manufacturer of the sterilizer [see 17.1 h)].

7.2.3 Each safety valve shall be mounted in an upright vertical position and each over-pressure protection device shall be connected to the vessel by the shortest practicable length of pipe.

7.2.4 Each over-pressure protection device having an enclosed discharge shall be individually piped to the atmosphere to terminate in a position that does not cause a safety hazard. If the discharge from the protection device is not visible from the sterilizer, the discharge pipe shall be provided with a small-bore pipe terminating at the sterilizer to give a visible indication of the discharge.

7.2.5 Pipework to an enclosed discharge shall have, wherever practicable, a continuous fall to the discharge point. If this cannot be achieved, the lowest part of any falling section shall be fitted with a condensate drain.

7.3 Process valves

The manufacturer shall retain the data that show each type of valve used is capable of operating correctly for a minimum of 2 000 operating cycles. These data shall be available to the purchaser, if requested (see Appendix A).

8 Hydraulic test

8.1 Vessels complying with 5.1.1, or with items a) or d) of 5.1.2

After construction (see clause 5), each vessel shall be subjected to the proof hydraulic test described in 5.8.6 or 5A.8.6 of BS 5500:1988.

8.2 Vessels complying with item b) of 5.1.2

8.2.1 Each vessel sampled from the batch (see 5.6.2) shall be subjected to the proof pressure test described in 4.3 of BS 1746:1987.

8.2.2 This test shall be carried out on all vessels modified by the sterilizer manufacturer.

8.3 Vessels complying with item c) of 5.1.2

Each vessel sampled from the batch (see 5.6.2) shall be subjected to the hydraulic test described in 5.8.6 of BS 5500:1988.

9 Airborne noise emission

No peak value of the A-weighted sound power level shall exceed the mean A-weighted sound power level by more than 15 dB [see also 17.1 i)].

Compliance is determined as described in Appendix D.

10 Thermal insulation

10.1 Asbestos products shall not be used for insulating purposes.

NOTE Thermal insulation should be installed in accordance with BS 5970.

10.2 Any surface that may attain a temperature exceeding 55 °C during normal operation shall be insulated, except where this would interfere with the operation of a component of the sterilizer, e.g. a safety valve [see also 17.1 c) and d)].

10.3 The temperature of the external surface of the insulation and the surface of parts of the sterilizer that could be inadvertently touched by the operator (see 10.2) during normal operation shall comply with clause 9 of ESCHLE⁶⁾.

11 Electrical requirements

11.1 General

Unless otherwise specified in this clause, the electrical system of the sterilizer shall comply with the requirements of ESCHLE⁶⁾ with the exception of clauses 3.2, 4.1, 4.2, 4.7, 4.8, 6.12, 10 and 12 of that document. The following sub-clauses shall replace or supplement the requirements specified in ESCHLE.

11.2 Power sources

11.2.1

NOTE This subclause replaces clause 4.8 of ESCHLE.

Means shall be provided for isolating the electrical equipment simultaneously from all poles of the mains supply. In addition, an emergency stop button or switch that will disconnect the electricity supply to the sterilizer shall be fitted within 1 m of each operator position. (See also clause 14 of ESCHLE.)

Compliance is checked by inspection and test.

11.2.2

NOTE 1 This subclause replaces clause 3.2 of ESCHLE.

⁶⁾ The Electrical Safety Code for Hospital Laboratory Equipment (see foreword).

Except where otherwise specified for specific tests, equipment shall be tested at the least favourable voltage between 90 % of the minimum rated voltage and 110 % of the maximum rated voltage. If operating controls and interchangeable components are provided, the tests shall be made with the controls in the least favourable positions and with the components fitted which will produce the most extreme electrical stress in the equipment.

If the mains supply fluctuates within $\pm 10\%$ of the nominal supply voltage (see note 2), the sterilizer shall be capable of being operated in accordance with the manufacturer's instructions and the requirements specified in the appropriate subsequent Part of BS 3970.

NOTE 2 Voltage fluctuations greater than $\pm 10\%$ but lasting less than 1 s may occur if equipment requiring a heavy current is connected to the same supply and is switched on or off.

Compliance is checked by direct test.

11.3 Marking of electrical characteristics

11.3.1

NOTE This subclause replaces item a) of clause 4.2 of ESCHLE.

The following details shall be marked on the outside of the equipment.

- a) The name of the manufacturer or supplier.
- b) An identification marking, for example model reference or serial number, that identifies uniquely the production batch of the equipment.
- c) For equipment which requires connection to protective earth for safety reasons, a statement to this effect marked adjacent to the supply mains input.
- d) For class II equipment, the following symbol⁷⁾ adjacent to the supply mains input.
- e) The rated voltage or voltage range. If the minimum and maximum supply voltages differ by more than 10 % from the mean value, these voltages shall be marked.

NOTE For equipment marked with a supply voltage range, the input voltage at the mean value of the range may be marked, if the minimum and maximum supply voltages do not differ from the mean value by more than 10 %.

Examples of markings.

a) 16A/220 V – 240 V/50 Hz

b) $\frac{1.6 \text{ kVa}}{380 \text{ V } 50 \text{ Hz } 3 \sim}$

f) The kind of current, if this is necessary for the safe use of the equipment: for example, d.c. or a.c. and, if more than one, the number of phases.

NOTE A statement of frequency, for example 50 Hz, is a satisfactory identification of the kind of current.

g) The rated supply mains frequency (in Hz), or frequency range.

h) The rated input (in W, kW, A, VA or kVA). If the equipment has one or more outlets providing an electrical supply to other equipment or parts, the marked power input of the sterilizer shall include the rated output of these outlets. The rated output of each outlet socket shall be marked.

11.3.2

NOTE This subclause replaces clause 4.7 of ESCHLE.

The following also apply.

a) The functions and positions of the controls of regulating devices, including switches, shall be marked.

NOTE Illumination by a labelled lamp may be used to satisfy this requirement.

b) The controls, instruments, indicating lamps, etc., which are associated with a separate function of the equipment, shall be grouped together and their function shall be marked or described in the accompanying instructions for use. If the misadjustment of controls can constitute a safety hazard, appropriate steps shall be taken to reduce this possibility, e.g. by introducing an interlocking device or an additional safety control.

c) Markings shall indicate the direction in which a control is to move in order to produce an increase (or decrease) in the effect regulated by the device. If the change in effect is indicated by numerals, higher numerals shall be used to show an increase in effect.

NOTE Clockwise rotation should normally produce an increase in effect.

If a regulatory control is combined with an ON/OFF switch, care should be taken to distinguish the numeral "zero" from the letter "O" if it is used to indicate "OFF".

Compliance is checked by inspection and functional test.

d) If a control switch or push button has an alternating action, e.g. push to turn ON, push again to turn OFF, there shall be a marking clearly describing this.

e) The colour of indicator lamps and push buttons shall comply with BS 4099-1.

⁷⁾ Symbol no. 02-01 of BS 7139.