

Autoclaves for sterilization in laboratories —

**Part 1: Specification for design,
construction, safety and performance**

Confirmed
December 2011

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Laboratory Apparatus Standards Policy Committee (LBC/-) to Technical Committee LBC/35, upon which the following bodies were represented:

- Association of British Health Care Industries
- Association of National Health Service Supplies Officers
- Association of Sterilizer and Disinfector Equipment Manufacturers
- British Dental Trade Association
- Central Sterilising Club
- Department of Health
- 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
- Society for General Microbiology
- Stainless Steel Fabricators' Association of Great Britain

The following bodies were also represented in the drafting of the standard, through subcommittees and panels:

- Association of Clinical Pathologists
- British Glass Manufacturers' Confederation
- British Laboratory Ware Association
- Copper Development Association
- Institute of Medical Laboratory Sciences
- Manufacturing Science Finance
- Ministry of Agriculture, Fisheries and Food
- Royal Association of British Dairy Farmers
- Society for Applied Bacteriology

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Foreword

This Part of BS 2646 has been prepared under the direction of the Laboratory Apparatus Standards Policy Committee. It specifies requirements for the design, construction, safety and performance of laboratory autoclaves for the purposes of sterilization. It does not cover autoclaves for use with material infected with organisms in Hazard Group 4 (see 1.1, footnote 3). This Part of BS 2646 supersedes BS 2646-1:1988 which is withdrawn. This new edition introduces requirements for function and performance, related to the methods of test contained in BS 2646-5.

BS 2646 comprises several separate Parts. The other Parts of the standard are as follows.

- *Part 2: Guide to planning and installation;*
- *Part 3: Guide to safe use and operation¹⁾;*
- *Part 4: Guide to maintenance;*
- *Part 5: Methods of test for function and performance.*

This Part of BS 2646 specifies requirements for the design and construction of the pressure vessel and also includes details of necessary pressure vessel and electrical safety features. It is intended that in conforming to this standard the design and manufacture of autoclave pressure vessels will also conform to the relevant requirements of BS 5500:1991.

It is acknowledged that copper and copper alloys are not covered by BS 5500, and neither are rectangular pressure vessels. The design criteria for autoclave pressure vessels constructed of copper or copper alloys and for rectangular chambers are included in this Part of BS 2646.

A section has also been included on steam generators heated by electricity where these form part of the autoclave unit.

This new edition of the standard introduces requirements for the performance and testing of autoclaves. Autoclaves may be suitable for a single process where the displacement of air is by steam, or they may be multi-purpose and incorporate a number of operating cycles for more than one process, some having a mechanical air removal system such as vacuum and/or a succession of pressure reductions and steam pulses. The testing programme is described in Annex A and covers tests on the pressure vessel and on the completed and installed autoclave, including commissioning. The tests themselves are described in BS 2646-5. Guidance on validation and in-use tests will be given in BS 2646-3.

Autoclaves covered by this standard are not intended for the sterilization of goods or fluids which are directly concerned with patient care nor for fabrics subjected to sterilization which are required to be dry at the end of the cycle. Sterilizers suitable for these applications are covered by Parts of BS 3970.

It is intended that consideration will be given to replacement of the references to BS 3456-101:1987 in 9.6, relating to electrical safety requirements, by references to BS EN 61010-1, when that standard is published. BS EN 61010-1 will include safety requirements for various types of laboratory equipment.

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

Enquiries as to the availability of third party certification schemes are 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.

¹⁾ In preparation.

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 36, 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.

Section 1. General

1.1 Scope

This Part of BS 2646 specifies requirements for the design, construction, safety and performance of autoclaves for operation with saturated steam at temperatures up to 138 °C and pressure not exceeding 2.4 bar²⁾ nominal and for operation under vacuum (subject to external pressure).

This standard covers laboratory autoclaves for the sterilization of goods and material which could be infected with organisms categorized as Hazard Group 1, 2 or 3³⁾. It does not cover autoclaves for use with material infected with organisms in Hazard Group 4, for which complete containment and sterilization of infected condensate is considered to be essential.

This standard does not apply to sterilizers or disinfectors used for medical, dental, pharmaceutical or veterinary purposes which are directly concerned with patient care, or to those used for fabrics subjected to sterilization which are required to be dry at the end of the cycle. These are covered by BS 3970.

1.2 References

1.2.1 Normative references

This Part of BS 2646 incorporates, by reference, provisions from specific editions of other publications. These normative references are cited at the appropriate points in the text and the publications are listed on page 35. Subsequent amendments to, or revisions of, any of these publications apply to this Part of BS 2646 only when incorporated in it by updating or revision.

1.2.2 Informative references

This Part of BS 2646 refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed on the inside back cover, but reference should be made to the latest editions.

1.3 Definitions

For the purposes of this Part of BS 2646, the following definitions apply.

1.3.1

autoclave

a machine, which incorporates a steam pressure vessel, designed to sterilize laboratory materials and equipment

NOTE It may also be used for other processes, such as heat disinfection and heat treatment, which may be selected according to the laboratory requirements and the nature of the load.

1.3.2

maximum permissible working pressure

the maximum internal pressure, not higher than the design pressure, at which the autoclave chamber and/or generator can be operated

NOTE To prevent unnecessary lifting of the safety valve, there should be an adequate margin between the actual pressure at which the autoclave is operating and the lowest pressure at which the safety valve is set to lift.

1.3.3

design pressure

the maximum internal pressure, not lower than the safety valve set pressure, that the autoclave chamber and/or generator is designed to withstand and that is therefore used in the design equations

1.3.4

safety valve set pressure

the pressure at which a safety valve is set to lift

1.3.5

operating pressure

the pressure at which the autoclave operates

1.3.6

design temperature

the saturated steam temperature corresponding to the design pressure of the autoclave chamber and/or generator. Its value is used to determine the appropriate nominal design strengths for the selected materials and is not lower than the actual metal temperature prevailing in service (see 5.3.1)

1.3.7

door

the closure of the autoclave chamber. In the case of a top loading autoclave, it is the lid of the chamber

1.3.8

purchaser

the individual or organization that buys the completed autoclave for its own use or as an agent for the user

1.3.9

manufacturer

the organization that designs, constructs and tests the autoclave in accordance with this Part of BS 2646 and with the purchaser's specification

²⁾ 1 bar = $1 \times 10^5 \text{ N/m}^2 = 0.1 \text{ N/mm}^2 = 1 \times 10^2 \text{ kPa} = 14.5038 \text{ lbf/in}^2$. Pressures referred to are measured from atmospheric and not on the absolute scale.

³⁾ The Hazard Groups of organisms referred to are those listed in *Categorization of pathogens according to hazard and categories of containment*, Second Edition, 1990 [1], produced by the Advisory Committee on Dangerous Pathogens, and published by HMSO.

NOTE By agreement, the design, construction and testing may be carried out by different organizations (see 1.5).

1.3.10 inspecting authority

the independent body or association appointed to check that the manufacturer's quality system, and the design, materials and construction of the autoclave pressure vessel(s) conform to this Part of BS 2646

1.3.11 regulating authority

the authority, in the country in which the autoclave is to be installed, that is legally charged with the enforcement of the requirements relating to autoclave pressure vessels of the law and regulations of that country

1.3.12 liquids sterilization

a process to sterilize a variety of liquids, including culture media, in containers of various types

NOTE Due to the heat sensitive nature of some constituents of nutrient media, time and temperature controls should allow the user to select cycle characteristics separately for each load.

1.3.13 make-safe

a process which reduces the microbial content of contaminated material so that it can be handled and disposed of without causing an infection hazard or environmental contamination

NOTE Material may include single-use items to be discarded, e.g. plastics specimen tubes and culture plates, and/or items for cleaning and reuse, e.g. glass containers and filter assemblies.

1.3.14 equipment and glassware sterilization

a process strictly limited to the sterilization of clean items which do not contain fluids

1.3.15 operating cycle

the complete set of stages of the autoclaving process carried out in the sequence regulated by the controller

1.3.16 sterilizing stage

the part of the operating cycle which comprises the equilibration time and the holding time

1.3.17 controller

a device which, in response to predetermined cycle variables, operates the autoclave through the required stages of the process in the correct sequence

1.3.18 operator

the person trained to use the autoclave

1.3.19 double-ended autoclave

an autoclave with a horizontally mounted chamber which has a door at each end

1.3.20 usable chamber space

the maximum volume of load which the chamber, with load support, is designed to accommodate

1.3.21 discard-container

a receptacle for material (including containers) to be subjected to a make-safe process

NOTE Guidance on the design of discard-containers is contained in *Safety in Health Service Laboratories — Safe working and the prevention of infection in clinical laboratories* [2], produced by the Health Services Advisory Committee and published by HMSO. Guidance will also be given in BS 2646-3.

1.3.22 container

a laboratory vessel in which liquids, including culture media, are processed in the autoclave

1.3.23 holding time

the period for which the chamber and load are at sterilizing temperature

NOTE The holding time may be set by the operator before the operating cycle commences but is not adjustable by the operator during the cycle.

1.3.24 sterilizing temperature

the temperature to be attained in all parts of the load throughout the holding time

NOTE The sterilizing temperature need not be the same for each process.

1.3.25 equilibration time

the period between attainment of the sterilizing temperature in the chamber drain (or vent) and in all points of the load

NOTE This has also been known as "load-lag".

1.3.26 steady state

a state in which the controlled temperature and corresponding pressure within the chamber are in equilibrium

1.3.27**commissioning**

the inspection and testing of the autoclave to confirm that it conforms to this Part of BS 2646 (see A.4)

1.3.28**performance tests**

the tests to be carried out at the time of manufacture, at the time of commissioning and subsequently during the life of the autoclave

1.3.29**validation**

the specified procedures which provide evidence that the particular operating cycle is capable of producing a repeatable assurance of effectiveness (see A.5)

1.3.30**fault**

the recognition by the controller or the operator that the predetermined or pre-set variables for the operating cycle have not been attained and that the process has been jeopardized

1.4 Classification**1.4.1 General**

Autoclaves are classified into types, according to the source of steam, (see 1.4.2) and into processes, according to the process(es) for which they are suitable (see 1.4.3).

1.4.2 Autoclave types

For the purposes of this Part of BS 2646, autoclaves are classified according to the source of steam as follows.

Type 1. Steam from an external source (see also 9.2.1).

Type 2. Steam from a generator forming part of the autoclave but capable of being isolated from the autoclave chamber, the generator being heated by means of an electric immersion heater see also 9.2.2).

Type 3. Steam from a generator, as in type 2, but without means of isolation from the autoclave chamber (see also 9.2.3).

Type 4. Steam produced from water contained within the autoclave chamber and heated by means of an electric immersion heater (see also 9.2.4).

1.4.3 Autoclave processes

Autoclave processes are as follows.

- a) Liquids sterilization (see 1.3.12).
- b) Make-safe (see 1.3.13).

- c) Equipment and glassware sterilization (see 1.3.14).

1.5 Responsibilities**1.5.1 Responsibilities of the purchaser**

The purchaser shall be responsible for supplying the manufacturer with the information specified in 1.6.1.

If there is a Regulating Authority, it shall be the responsibility of the purchaser to ensure before the order is placed, that the Inspecting Authority is acceptable to the Regulating Authority.

1.5.2 Responsibilities of the manufacturer

1.5.2.1 The manufacturer shall be responsible for the completeness and accuracy of all design calculations and for conformity of the whole autoclave to the relevant requirements of this Part of BS 2646. If, during fabrication or design of the autoclave or pressure vessel, unexpected factors arise which justify deviations from the specified requirements but which do not affect the safety as intended by this Part of BS 2646, such deviations shall be submitted to the purchaser for approval and shall be recorded in accordance with item c) of 1.6.2.3.

1.5.2.2 If the design and fabrication functions are carried out by separate organizations, the manufacturer's responsibilities as laid down in this standard shall be discharged in a manner agreed and documented by the parties concerned in accordance with item a) of 1.6.3.

1.5.2.3 Examinations of a pressure vessel carried out by the Inspecting Authority shall not absolve the manufacturer from his responsibility for compliance with the relevant requirements of this Part of BS 2646.

1.5.2.4 The manufacturer shall be responsible for supplying the Inspecting Authority with two copies of the information specified in 1.6.2.2 for each autoclave pressure vessel or batch of nominally identical vessels serially produced.

1.5.2.5 The manufacturer shall be responsible for supplying the purchaser with the information specified in 1.6.2.3, and for making it also available to the Inspecting Authority and the Regulating Authority.

1.5.3 Responsibilities of the Inspecting Authority

The Inspecting Authority shall be responsible for checking the design of the autoclave pressure vessel for conformity to this Part of BS 2646. The Inspecting Authority shall be responsible for inspection and testing as specified in section 7.

Certificate of compliance (to be completed for each pressure vessel)*Autoclave type*

Vessel description

Boiler/receiver

Approximate internal dimensions

Approved drawing number(s)

.....

.....

Manufacture

Year of manufacture

Name of manufacturer

Manufacturer's serial no. or cipher (see note)

Name of Design Organization
(if other than manufacturer)

Name of Inspecting Authority,
design approval

Name of Inspecting Authority, testing
and inspection (where appointed)

Design

Design pressure (in bar)

Design temperature (in °C)

Construction category

<i>Post welded heat treatment (where applicable)</i>	Component	Temperature (in °C)	Holding time (in h)
.....			

<i>Hydraulic pressure test</i>	Location	Test pressure (in bar)	Test medium and temperature (in °C)	Date
.....				

Deviations and concessions

NOTE. The suffix 'XX' is to be added to the serial number of each vessel for which any deviations or concessions have been authorized (see item c) of 1.6.2.3).

Figure 1 — Certificate of compliance (*continued*)

Certificate of compliance (design)

We hereby certify that the design of this vessel conforms to BS 2646 : Part 1 : 1993, and has been approved by

(Name of Inspecting Authority)

Reference of Inspecting Authority, approval

For manufacturer Date

Position Name of company

Certificate of compliance (construction and testing)

We hereby certify that this vessel has been constructed and tested and conforms to BS 2646 : Part 1 : 1993.

For manufacturer Date

Position Name of company

This section to be completed if an Inspecting Authority has been appointed to examine and test this pressure vessel

We hereby confirm that the above vessel has been examined and tested and that to the best of our knowledge and belief it conforms to BS 2646 : Part 1 : 1993.

For Inspecting Authority Date

Position

Name of company (where relevant)

Figure 1 — Certificate of compliance (concluded)

1.5.4 Certificate of compliance

On completion of construction of the pressure vessel, the manufacturer shall issue a certificate of compliance (see Figure 1) to certify that the vessel has been designed, constructed and tested in every respect in accordance with this Part of BS 2646. The certificate of compliance shall be countersigned by the Inspecting Authority if such an authority has been appointed.

1.6 Information and requirements to be agreed and to be documented

1.6.1 Information to be supplied by the purchaser

The following information shall be supplied by the purchaser, if required by the manufacturer, and shall be fully documented. Documented items shall be satisfied before a claim of compliance with this Part of BS 2646 can be made and verified.

- a) A specification of the normal working conditions of the autoclave together with details of any transient and/or adverse conditions under which the autoclave is required to operate and of any special regulations for in-service inspection.
- b) Any additional requirements not given in this standard.
- c) Any special statutory or other regulations with which a finished autoclave pressure vessel is required to comply.
- d) The name of the Regulating Authority (if any).
- e) Whether or not an Inspecting Authority is to be nominated by the purchaser (see 7.1).
- f) If an Inspecting Authority is to be nominated by the purchaser, the name of the Inspecting Authority.

1.6.2 Information to be supplied by the manufacturer

1.6.2.1 The information listed in 1.6.2.2 to 1.6.2.4 shall be supplied by the manufacturer and shall be fully documented. Both the definitive requirements of this Part of BS 2646 and the agreed and documented items (see 1.6.3) shall be satisfied before a claim of compliance with this Part of BS 2646 can be made and verified.

1.6.2.2 For each autoclave pressure vessel or batch of nominally identical vessels serially produced, the manufacturer shall supply the Inspecting Authority with two copies of the information detailed in items a) to e), as follows.

- a) A fully dimensioned drawing of the vessel, as designed, together with any relevant supporting information in accordance with 4.1.1 of BS 5500:1991 which is not covered by items b) to e) or by 1.6.2.3.

b) A list of materials (including welding consumables) used in the construction of the vessel(s), together with details of any special heat treatments carried out by the material supplier. For materials for which compliance with a British Standard is claimed, the date of the standard shall be given.

c) Any requirements for non-destructive testing of the pressure vessel in accordance with clause 7.5 (for aluminium alloy vessels only).

d) The welding procedures used during vessel manufacture (see 7.2.3).

e) Any procedures used for inspection and/or crack detection of welds (see 7.6.1).

1.6.2.3 The manufacturer shall supply the purchaser with the following information, which shall also be available to the Inspecting Authority and the Regulating Authority.

- a) A certificate of compliance for each pressure vessel (see 1.5.4).
- b) A facsimile of the marking as required by section 13.
- c) Records of authorized deviations or concessions (see 1.5.2.1). The manufacturer shall add the suffix "XX" to the serial number of each vessel and autoclave for which any deviation or concessions have been authorized.
- d) Details of any alternative specifications in this standard which require the approval of the purchaser (see 1.6.3).
- e) Details of the services required on site for the satisfactory operation of the autoclave.
- f) If an Inspecting Authority is to be nominated by the manufacturer, the name of the Inspecting Authority.

1.6.2.4 The manufacturer shall indicate to the purchaser, for each relevant autoclave process (see 1.4.3), the duration of the operating cycle as measured in accordance with BS 2646-5:1993, provided that the autoclave performance conforms to section 12 of this Part of BS 2646. Where the alternative test(s) B or C have been performed, details of the challenge load, including the load container(s) and/or discard-container(s) shall also be provided.

1.6.3 Items to be agreed and documented

The following items to be agreed, as appropriate, between the parties concerned, which are specified in the clauses referred to, shall be fully documented. Both the definitive requirements specified throughout this standard and the following documented items shall be satisfied before a claim of compliance with this standard can be made and verified.

- a) The manner in which the manufacturer's responsibilities are to be discharged in cases where the design and fabrication functions are carried out by separate organizations (see 1.5.2.2).
- b) The use of materials of construction that are not listed in Table 1 or Table 2 (see item b) of 1.6.2.2).
- c) Whether welder approval tests that have been completed to the satisfaction of another recognized Inspecting Authority are acceptable (see note 2 of 7.3.4).
- d) Acceptance criteria for defects revealed by visual examination, including aided visual examination (see 7.6.1).
- e) The autoclave type (see 1.4.2).
- f) The process(es) for which the autoclave is suitable (see 1.4.3).
- g) The nature of loads for which the autoclave is to be used (see A.5).
- h) Any specific requirements which may be evident to the purchaser or manufacturer after consideration of the guidance given in BS 2646-2:1990, BS 2646-3 and BS 2646-4:1991.

NOTE A list of optional requirements is contained in Annex B.

Section 2. Materials

2.1 Selection of materials

2.1.1 General

2.1.1.1 The selection of the materials of construction for pressure-containing parts and their integral attachments shall take into account the suitability of the material with regard to fabrication and to the conditions under which they will eventually operate. Due attention shall be paid to the effects of galvanic attack and differential expansion when dissimilar metals are used in contact and also to the susceptibility of some stainless steels to stress and crevice corrosion.

2.1.1.2 The materials used in the manufacture of pressure-containing parts shall be one of the following:

- a) materials conforming to the appropriate British Standard listed in Table 1 and Table 2;

b) other materials, subject to agreement with the Inspecting Authority and the purchaser (see item b) of **1.6.3**).

2.1.2 Welding and brazing materials

2.1.2.1 Welding materials for autoclaves constructed from materials listed in Table 1 shall be selected in accordance with **4.3.2** of BS 5500:1991 or **4.3.2** of Annex AA of BS 5500:1991.

2.1.2.2 Brazing materials for the copper and copper alloys listed in Table 2 shall be in accordance with **6.4**.

2.2 Nominal design strength

The nominal design strength of every material used in the manufacture of the shell and ends of the autoclave chamber and generator, including the door and frame, shall, as appropriate, be as listed or referred to in Table 1 and Table 2.