

BS 2646-1:2021



BSI Standards Publication

Autoclaves for sterilization in laboratories

Part 1: Design, construction, safety and performance —
Specification

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Foreword

Publishing information

This part of BS 2646 is published by BSI Standards Limited, under licence from The British Standards Institution, and came into effect on 30 April 2021. It was prepared by Technical Committee CH/198, *Sterilization and Associated Equipment and Processes*. A list of organizations represented on this committee can be obtained on request to its committee manager.

Supersession

This part of BS 2646 supersedes [BS 2646-1:1993](#) and [BS 2646-5:1993](#), which are withdrawn.

Relationship with other publications

BS 2646 is published in four parts. The other parts of the standard are as follows:

- Part 2: *Guide to planning and installation*;
- Part 3: *Guide to safe use and operation*;
- Part 4: *Guide to maintenance*.

Information about this document

This part of BS 2646 updates and combines [BS 2646-1:1993](#) and [BS 2646-5:1993](#), bringing together the design and performance requirements of the [BS 2646-1:1993](#) with the test requirements that verify that performance from [BS 2646-5:1993](#).

This revision aligns [BS 2646-1](#) with the Supply of Machinery (Safety) Regulations 2008 [1] which implemented Directive 2006/42/EC [2] on machinery and incorporates the requirements of the BS EN 61010-1 series of safety standards. It aligns its pressure vessel requirements with the Pressure Equipment Directive [3], the UK's PD 5500 for unfired pressure vessels and the BS EN 13445 series of standards for unfired pressure vessels where relevant.

The standard incorporates significant changes to the testing regime for new autoclaves and allows for type testing of autoclave models. Instrumentation and control requirements have been updated to reflect current state of the art technology.

This publication can be withdrawn, revised, partially superseded or superseded. Information regarding the status of this publication can be found in the Standards Catalogue on the BSI website at bsigroup.com/standards, or by contacting the Customer Services team.

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Presentation conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Requirements in this standard are drafted in accordance with *Rules for the structure and drafting of UK standards*, subclause G.1.1, which states, "Requirements should be expressed using wording such as: 'When tested as described in [Annex A](#), the product shall ...'". This means that only those products that are capable of passing the specified test will be deemed to conform to this standard.

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1 Scope

This part of BS 2646 specifies requirements for the design, construction, safety and performance of autoclaves for operation with saturated steam and for operation under vacuum (subject to external pressure).

This part of BS 2646 covers laboratory autoclaves for the sterilization of goods and material which could be infected with organisms, the sterilization of growth media or other materials required for the operation of a laboratory.

This part of BS 2646 does not apply to sterilizers or disinfectors used for pharmaceutical production or medical purposes directly concerned with patient care.

NOTE These are covered by BS EN 285 or BS EN 13060 and [BS 3970-2](#).

This part of BS 2646 does not apply to autoclaves utilizing a fired pressure vessel.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions of this document¹⁾. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS 3693, *Recommendations for design of scales and indexes on analogue indicating instruments*

BS 6253-1, *Electrical measuring transducers for converting a.c. electrical quantities into d.c. electrical quantities – Part 1: Method for specifying general purpose transducers*

BS EN 285, *Sterilization – Steam sterilizers – Large sterilizers*

BS EN 764-7, *Pressure equipment – Part 7: Safety systems for unfired pressure vessels*

BS EN 837-1, *Pressure gauges – Part 1: Bourdon tube pressure gauges – Dimensions, metrology, requirements and testing*

BS EN 13190, *Dial thermometers*

BS EN 13445 (all parts), *Unfired pressure vessels*

BS EN 14222, *Stainless steel steam boilers*

BS EN 60584-1, *Thermocouples – Part 1: EMF specifications and tolerances*

BS EN 60688, *Electrical measuring transducers for converting A.C. and D.C. electrical quantities to analogue or digital signals*

BS EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors*

BS EN 60770-1, *Transmitters for use in industrial-process control systems – Part 1: Methods for performance evaluation*

BS EN 61010-1:2010+A1:2019, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

BS EN 61010-2-040, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

BS EN 61326-1, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

¹⁾ Documents that are referred to solely in an informative manner are listed in the Bibliography.

[BS EN 61508](#), *Functional safety of electrical/electronic/programmable electronic safety-related systems*

BS EN ISO 4126-1:2013+A2:2019, *Safety devices for protection against excessive pressure – Part 1: Safety valves*

BS EN ISO 4796-1, *Laboratory glassware – Bottles – Part 1: Screw-neck bottles*

BS EN ISO 13732-1, *Ergonomics of the thermal environment – Methods for the assessment of human responses to contact with surfaces – Hot surfaces*

BS EN ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

PD 5304, *Guidance on safe use of machinery*

PD 5500, *Specification for unfired pressure vessels*

3 Terms and definitions

For the purposes of this part of BS 2646, the following terms and definitions apply.

3.1 approved body

organization responsible for assessing and certifying conformity to relevant British Standards

NOTE For example, an approved body may provide conformity assessment against PD 5500:2018+A2:2019 in order that a UKCA mark can be applied.

3.2 autoclave

machine incorporating a steam pressure vessel, designed to sterilize or process laboratory materials, waste and equipment

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

3.3 construction code

national or international standard to which pressure vessels are designed and manufactured

3.4 controller

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

3.5 design temperature

saturated steam temperature corresponding to the maximum working pressure of the autoclave chamber and/or generator

NOTE 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.

3.6 discard container

receptacle for material (including containers) 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 and similar facilities* [4]. Guidance is also given in [BS 2646-3](#).

3.7 double door autoclave

autoclave with a door at each end of the chamber

NOTE Also known as a pass through or double-ended autoclave.

3.8 effluent retention

retention of the liquid in the chamber so that all micro-organisms present in the chamber are exposed to the required sterilization temperature for the required time

NOTE 1 Alternatively the liquid may be held in a secondary processing chamber for sterilization separately from the load.

NOTE 2 Effluent retention is often combined with exhaust filtration.

3.9 equilibration time

period between attainment of the sterilizing temperature at the control probe and in all points of the load

NOTE This is also known as "load-lag" or stabilization time.

3.10 equipment and glassware sterilization

process for the sterilization of clean items which do not contain fluids

3.11 fabrics and textiles disinfection

processing of fabrics and/or textiles so that they are safe for further use, laundering or disposal

3.12 functional test

inspection and testing of the autoclave's safety devices, instrument accuracy and performance

3.13 holding time

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

3.14 liquids sterilization

process for sterilizing a variety of liquids, including culture media

3.15 make-safe

process to reduce the microbial content of contaminated material so that it can be handled and disposed of without causing an infection hazard

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.

3.16 manufacturer

organization that designs, constructs and tests the autoclave

NOTE By agreement, the design, construction and testing may be carried out by different organizations (see [Clause 5](#)).

3.17 materials testing and processing

process where sterilization or disinfection might not be the required outcome

NOTE For example, life cycle testing.

3.18 notified body

organization responsible for assessing and certifying conformity to relevant European Standards

NOTE For example, a notified body may provide conformity assessment against BE EN 13445 in order that a CE mark can be applied.

3.19 operating cycle

complete set of stages of a process carried out in a specified sequence

3.20 operating pressure

fluid pressure occurring during an operating cycle

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

3.21 operator

person trained to use the autoclave

3.22 performance test

specified procedures which provide evidence that the particular operating cycle consistently produces a product which meets all predefined requirements

3.23 purchaser

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

3.24 regulating authority

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

3.25 sterilizing temperature

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

3.26 usable chamber space

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

4 Classification**4.1 Autoclave class**

Autoclaves shall be classified in accordance with the source of steam as follows.

- a) *Class 1.* Steam from an external source, not controlled by the autoclave.
- b) *Class 2.* Steam from a generator forming part of and controlled by the autoclave but capable of being isolated from the autoclave chamber.
- c) *Class 3.* Steam from a generator, as in class 2, but without means of isolation from the autoclave chamber.
- d) *Class 4.* Steam produced from water contained and heated within the autoclave chamber.

NOTE Where the method of generation of steam is not controlled by the autoclave system, these are classified as class 1.

4.2 Autoclave processes

Autoclave processes shall be classified as follows:

- a) liquids sterilization (see [3.14](#));
- b) make-safe (see [3.15](#));

- c) equipment and glassware sterilization (see [3.10](#));
 - d) fabrics and textiles disinfection (see [3.11](#)); and
 - e) materials testing and processing (see [3.17](#)).
-

5 Responsibilities

5.1 Responsibilities of the manufacturer

- 5.1.1** 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.
- 5.1.2** If the design and fabrication functions are carried out by separate organizations, the manufacturer's responsibilities, in accordance with this part of BS 2646, shall be discharged as agreed and documented by the parties concerned in accordance with [6a](#)).
- 5.1.3** Examinations of a pressure vessel carried out by the UK-approved body or notified body shall not absolve the manufacturer from their responsibility for conformity to the relevant requirements of this part of BS 2646.
- 5.1.4** The manufacturer shall be responsible for supplying the purchaser with the information specified in Clause [6](#) and for making it also available to the regulating authority.

5.2 Certificate of compliance

On completion of construction of the pressure vessel, the manufacturer shall issue a certificate of compliance/declaration of conformity to certify that the vessel has been designed, constructed and tested in accordance with its construction code.

6 Information and requirements to be agreed, documented and supplied by the manufacturer

For each autoclave pressure vessel or batch of nominally identical vessels serially produced, the manufacturer shall supply the purchaser with a copy of the certificate issued by a UK-approved body or Notified Body stating conformity to the relevant section of PD 5500 and/or BS EN 13445 (all parts).

The manufacturer shall make available, on request to the purchaser, the following information, which shall also be available to the regulating authority:

- a) certificate of compliance for each pressure vessel (see [5.2](#));
- b) facsimile of the marking in accordance with [Clause 13](#);
- c) details of any deviations from this British Standard and their justification; and
- d) details of the services required on site for the satisfactory operation of the autoclave.
For classification 2, 3 and 4 this shall include the quality of the feed water to be used for steam generation.

NOTE 1 See [4.1](#) for the autoclave classification.

NOTE 2 See [4.2](#) and [Annex A](#) for the process(es) and nature of the loads for which the autoclave is suitable.

7 Selection of materials

- 7.1** 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 are to operate.
- 7.2** The effects of galvanic attack and differential expansion when dissimilar metals are used in contact shall be taken into account, including the susceptibility of some materials to stress and crevice corrosion. The materials used shall also be selected in accordance with the heating and cooling cycles required.
- 7.3** The materials used in the manufacture of pressure-containing parts shall be selected in accordance with the requirements of PD 5500 or BS EN 13445-2.
- 7.4** Welding materials for pressure parts shall be selected in accordance with PD 5500 or BS EN 13445-2.
- 7.5** Brazing materials for pressure parts shall be selected in accordance with PD 5500 or BS EN 13445-2.
- 7.6** Materials in contact with steam or condensate shall:
- a) resist attack from steam or condensate;
 - b) not cause deterioration of the quality of the steam or of the items of which the autoclave is designed to process; and
 - c) not release any substances known to be toxic in such quantities that could create a health or environmental hazard.

NOTE See [Annex B](#) with regard to environmental aspects.

8 Autoclave chamber

8.1 General

The autoclave chamber shall be either front loading or top loading. The interior of the chamber shall allow condensate to drain away from and steam to circulate to all parts of the load.

8.2 Chamber doors

8.2.1 Chambers can be fitted with a single door or with separate doors for loading and unloading.

8.2.2 Doors shall be classified by the following types:

- a) manually-operated quick action closure (see [14.4.2](#));
- b) power-operated closure where the door closure is operated automatically by a single action by the operator or semi-automatically, where the door closure is actuated by a continuous action by the operator, e.g. holding a button until the closure action is completed (see [14.4.4](#)); and
- c) single or multi-bolt closure (see [14.4.3](#)).

8.3 Test connections

Test connections for temperature and pressure sensors shall be provided.

A test connection shall provide direct connection with the sterilizer chamber providing it causes no adverse effect on the measurement of the pressure in the sterilizer chamber.

A straight connecting sleeve shall be provided to pass temperature measurement sensors into the chamber. The size of the connecting sleeve shall enable insertion of all the temperature sensors required to undertake performance testing in accordance with [Clause 21](#).

NOTE It might be beneficial to identify the test connections as PT (pressure test) and TT (temperature test).

9 Steam generators

Steam generators shall be fitted to autoclaves, classification 2 and 3 (see [4.1](#)). The steam generator shall be designed and installed to permit access for inspection and cleaning.

NOTE BS EN 14222 provides guidance on operation of steam boilers.

10 Design and manufacture

10.1 General

Except where otherwise stated, the application of design criteria and formulae shall conform to the PD 5500 and/or BS EN 13445 (all parts).

NOTE Attention is given to the Pressure Equipment Directive [\[3\]](#).

10.2 Pipework assemblies

- 10.2.1 The pipework and fittings that are used as part of the autoclave pressure system shall be constructed from materials suitable for that purpose.
- 10.2.2 The door seal shall be a replaceable component.
- 10.2.3 Connecting compounds shall not be used to attach the door seal to the door or chamber.
- 10.2.4 The face of the door seal shall be completely exposed for inspection, cleaning and replacement purposes when the door is open. It shall be possible to replace the door seal without the need to dismantle the door assembly.

11 Type testing

For autoclaves that are produced to the same type, it shall be acceptable to undertake factory functional testing of the individual cycle types and a subsection of the tests described in [Clause 20](#) and [Clause 21](#), which may be limited to a test to prove that a cycle performs correctly if the full tests described in [Clause 20](#) and [Clause 21](#) have been undertaken for that type of autoclave.

Autoclaves classed as the same type shall have:

- a) the same number of doors in the same configuration;

NOTE 1 Where it has been demonstrated that for a given size and type of autoclave door, there is no difference in the influence on the load between an autoclave door and a back plate, autoclaves with one or two of these autoclave doors do not constitute different types.

- b) all service connections into the autoclave chamber in the same orientation;

NOTE 2 A mirror image of the original orientation does not constitute a new type.

- c) the same control system with all sensors located in the same position and orientation; any change in the control system that does not affect the operating cycle and the limiting values; and
- d) the same operating cycle.

If all other aspects of design remain the same the following variations shall not constitute a new type:

- 1) height of autoclave chamber location above the floor;
- 2) differences in the dimensions of the autoclave chamber not greater than $\pm 10\%$ of the dimensions with congruent autoclave chamber shapes;
- 3) increasing the time of the plateau period within the operating cycle having the same sterilization temperature and the same air removal stage; and
- 4) any change of the design or provenance of equipment providing there is available documented evidence to show there is no adverse effect on the performance of the autoclave which would affect conformity to this British Standard.

12 Inspection and testing of pressure vessels

12.1 General

Each pressure vessel shall be manufactured under a quality system in accordance with the relevant construction code.

12.2 Marking of pressure vessels, doors and safety valves

Each pressure vessel, door and safety valve shall be legibly and permanently marked on the vessel, door and/or safety valve, or on a permanently attached name plate, with the manufacturer's cipher identifying the item in accordance with the construction code (see [Clause 12](#)).

The pressure vessel shall be marked in accordance with BS EN 61010-1:2010+A1:2019, Clause 5.

13 Inspection and testing of the completed autoclave

13.1 General

In addition to inspections during manufacture, final inspections and tests on safety devices in accordance with this clause and [Clause 20](#) shall be carried out on the completed autoclave at the manufacturer's premises.

NOTE By agreement between the manufacturer and purchaser, the final works inspection and tests, including those carried out on instrument accuracy and the control system, may be carried out in the presence of representatives of the purchaser.

13.2 Factory functional testing

13.2.1 The manufacturer shall functionally test the autoclave prior to dispatch.

13.2.2 Functional tests shall comprise:

- a) inspections and tests on safety devices (in accordance with this subclause and [Clause 20](#));
- b) tests on instrument accuracy and the control system (see [21.1](#)); and
- c) autoclave performance tests in accordance with [21.2](#) to [21.7](#) (where applicable) and in accordance with the manufacturer's agreed schedule.

14 Product safety and safety devices

14.1 General

NOTE This clause specifies the provision and design of safety devices and attachments concerned with the pressure vessel(s) of the autoclave and also electrical safety and surface temperatures.

Unless otherwise stated, conformity to the requirements of [14.2](#) shall be checked by visual inspection and/or calculation and, where practicable, by direct measurement.

14.2 Provision of pressure vessel safety devices

14.2.1 Safety devices for autoclaves of class 1

Chambers of class 1 autoclaves shall be fitted with the following safety devices:

- a) a safety valve conforming to [14.3](#);
- b) a steam pressure gauge conforming to [16.2](#);
- c) means for attaching a test pressure gauge to facilitate transfer calibration of the gauge in b), if required by the purchaser;
- d) an automatic device or suitable reducing valve which prevents the manufacturer's recommended safe working pressure being exceeded; and

NOTE The reducing valve may be provided by a third party.

- e) two manually operated isolation valves fitted upstream of the reducing valve or device.

14.2.2 Safety devices for autoclaves of class 2

Chambers of class 2 autoclaves shall be fitted with the following safety devices:

- a) an automatic device, reducing valve or control system which prevents the safe working pressure of the chamber being exceeded;
- b) a safety valve conforming to [14.3](#);
- c) a steam pressure gauge conforming to [16.2](#); and
- d) means for attaching a test pressure gauge to facilitate transfer calibration of the gauge in c), if required by the purchaser.

Steam generators of class 2 autoclaves shall be fitted with the following safety devices:

- 1) a safety valve conforming to [14.3](#);
- 2) a steam pressure gauge conforming to [16.2](#);
- 3) a water level control device, including a means of indicating that the water level is maintained at the required level;
- 4) a device which disconnects the energy supply to the heat source when a set water level is detected. The device shall be resettable to reconnect the energy supply. If an over-temperature thermostat is used for this purpose, it shall not be part of the process control system; and
- 5) means for attaching a test pressure gauge if required by the purchaser.

14.2.3 Safety devices for autoclaves of class 3 and class 4

Chamber and steam generator assemblies of class 3 autoclaves shall be fitted with the following safety devices:

- a) a safety valve conforming to [14.3](#);
- b) a steam pressure gauge conforming to [16.2](#), connected to the chamber;
- c) a water level control device, including a means of indicating that the water level is maintained at the required level;