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BS 2646-1:2021



BSI Standards Publication

Autoclaves for sterilization in laboratories

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

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Published by BSI Standards Limited 2021

ISBN 978 0 539 04602 1

ICS 11.080.10; 71.040.10

The following BSI references relate to the work on this document:

Committee reference CH/198

Draft for comment 20/30394635 DC

Amendments/corrigenda issued since publication

Date	Text affected
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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This part of BS 2646 supersedes [BS 2646-1:1993](#) and [BS 2646-5:1993](#), which are withdrawn.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This publication can be withdrawn, revised, partially superseded or superseded.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.

Where websites and webpages have been cited, they are provided for ease of reference and are correct at the time of publication. The location of a webpage or website, or its contents, cannot be guaranteed.

Presentational 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.