

ROOSTEVABAST TERASEST AURUBOILERID

Stainless steel steam boilers

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN 14222:2021+A1:2025 sisaldab Euroopa standardi EN 14222:2021+A1:2025 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.09.2025.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN 14222:2021+A1:2025 consists of the English text of the European standard EN 14222:2021+A1:2025.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 03.09.2025.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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English Version

Stainless steel steam boilers

Chaudières à vapeur en acier inoxydable

Edelstahl-Dampfkessel

This European Standard was approved by CEN on 13 December 2020 and includes Amendment 1 approved by CEN on 16 April 2025.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 14222:2021+A1:2025) has been prepared by Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2026, and conflicting national standards shall be withdrawn at the latest by March 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes A1 EN 14222:2021 A1.

This document includes Amendment 1 approved by CEN on 16 April 2025.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

A1 This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, and Annex ZB, which are integral parts of this document. A1

Further to the updating both technically and editorially, the following changes compared to the previous edition have been made:

- in the title “shell” has been changed to “steam” to read: “stainless steel steam boilers”;
- Scope has been refined by replacing “allowable pressure (PS) of 6 bar” by “allowable pressure (PS) of not greater than 6 bar”;
- Introduction added;
- Normative references and Bibliography have been updated;
- alignment of terminology throughout the document;
- definition of “limiter” has been aligned with EN 12953-9 and new definition of “steam boiler” was introduced;
- requirements on materials have been aligned with new edition of EN 13445-2;
- general requirements for equipment (see 9.1) have been revised, e.g. requirements on materials in contact with steam added;
- requirements on limiting devices and safety circuits (see 9.4) have been fundamentally revised;
- requirements on steam boiler heat supply revised by adding cross-references to requirements of EN 285:2015+A1:2021, or EN 13060:2014+A1:2018 (see 9.5);

- the option of the use of an safety temperature limiter instead of a water level limiter has been addressed (see 9.6.3);
- requirements on steam pressure indication have been revised by adding reference to small steam sterilizers (see 9.7.1);
- requirements on limiter regarding low water protection (see 9.12.1) have been fundamentally revised;
- **A1** removal of informative Annex B on Guidance on the intended relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 on medical devices aimed to be covered;
- update of Annex ZA on the Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered;
- update of Annex ZB on the Relationship between this European Standard and the essential requirements of Directive 2014/68/EU on Pressure Equipment aimed to be covered **A1**.

A1 Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website. **A1**

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Introduction

EN 14222 is referred to normatively in [EN 285:2015+A1:2021](#), *Sterilization — Steam sterilizers — Large sterilizers* and can be applied to [EN 13060:2014+A1:2018](#), *Small steam sterilizers*, two standards developed by CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices”.

During the systematic review of EN 14222:2003 in 2014, CEN/TC 102 identified and expressed that the standard needed revising to bring it to the state of the art, and hence to enhance the requirements contained in [EN 285:2015+A1:2021](#) and [EN 13060:2014+A1:2018](#).

This document refers to [EN 12953](#), *Shell boilers* and [EN 13445](#), *Unfired pressure vessels*.

1 Scope

This document specifies requirements for electrically heated steam boilers manufactured from stainless steel specifically dedicated for generating steam for sterilizers and disinfectors.

This document covers only steam boilers that are heated by immersion heaters and which have a maximum allowable pressure (PS) of not greater than 6 bar, a maximum volume (V) of 1 000 litres and a product of $PS \cdot V$ not greater than 3 000 bar · l.

2 Normative references

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

EN 285:2015+A1:2021, *Sterilization — Steam sterilizers — Large sterilizers* A1

EN 764-1:2015+A1:2016, *Pressure equipment — Part 1: Vocabulary*

EN 12953-1:2012, *Shell boilers — Part 1: General*

EN 12953-5:2020, *Shell boilers — Part 5: Inspection during construction, documentation and marking of pressure parts of the boiler*

EN 12953-6:2024, *Shell boilers — Part 6: Requirements for equipment for the boiler* A1

EN 12953-8:2001,¹⁾ *Shell boilers — Part 8: Requirements for safeguards against excessive pressure* A1

EN 12953-9:2024, *Shell boilers — Part 9: Requirements for limiting devices of the boiler and accessories* A1

EN 13060:2014+A1:2018, *Small steam sterilizers*

EN 13445-2:2021+A1:2023, *Unfired pressure vessels — Part 2: Materials* A1

EN 13445-3:2021, *Unfired pressure vessels — Part 3: Design* A1

EN 13445-4:2021+A1:2023, *Unfired pressure vessels — Part 4: Fabrication* A1

EN 13445-5:2021+A1:2024, *Unfired pressure vessels — Part 5: Inspection and testing* A1

EN 14597:2012, *Temperature control devices and temperature limiters for heat generating systems*

EN 60204-1:2018,²⁾ *Safety of machinery — Electrical equipment of machines — Part 1: General requirements (IEC 60204-1:2016)* A1

EN 61010-1:2010,³⁾ *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements (IEC 61010-1:2010)*

1) This document is impacted by corrigendum EN 12953-8:2001/AC:2002.

2) This document is impacted by amendment EN 60204-1:2018/A1:2025.

EN IEC 61010-2-040:2021, *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 (IEC 61010-2-040:2020)* ^{A1}

EN IEC 62061:2021,⁴⁾ *Safety of machinery — Functional safety of safety-related control systems (IEC 62061:2021)* ^{A1}

EN ISO 11139:2018,⁵⁾ *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018)* ^{A1}

EN ISO 13849-1:2023, *Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design (ISO 13849-1:2023)* ^{A1}

EN ISO 13849-2:2012, *Safety of machinery — Safety-related parts of control systems — Part 2: Validation (ISO 13849-2:2012)*

3 Terms and definitions

For the purposes of this document, the terms and definitions of the pressure equipment directive (PED), and terms and definitions given in EN 764-1:2015+A1:2016, EN 12953-1:2012 and EN 12953-6:2024 ^{A1}, and the following apply.

In case of conflicts with terms defined in EN ISO 11139:2018, the terms from the PED have priority.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

control

regulation of variables within specified limits

Note 1 to entry: For example, water level, pressure, temperature.

[SOURCE: EN ISO 11139:2018, 3.63 — modified: Note 1 to entry added.]

3.2

limiter

limiting device that, on reaching a fixed value is used to interrupt and lock-out the heating energy supply

Note 1 to entry: Limiting device comprises

- a measuring or detection function;
- an activation function or correction, or shutdown, or shutdown and lock out, and which is used to carry out safety related functions as defined in the PED, on its own or as part of safety (protective) system (e.g. sensors,

3) This document is impacted by amendment EN 61010-1:2010/A1:2019 and corrigendum EN 61010-1:2010/A1:2019/AC:2019-04.

4) This document is impacted by amendment EN IEC 62061:2021/A1:2024.

5) This document is impacted by amendment EN ISO 11139:2018/A1:2024.