

ROOSTEVABAST TERASEST AURUBOILERID

Stainless steel steam boilers

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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ICS 27.060.30

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EUROPEAN STANDARD

EN 14222

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2021

ICS 27.060.30

Supersedes EN 14222:2003

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.

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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN 14222:2021) 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of an identical text or by endorsement, at the latest by July 2021, and conflicting national standards shall be withdrawn at the latest by July 2021.

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 EN 14222:2003.

This document has been prepared under mandates (M/071 and M/023) given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annexes ZA and ZB, which are an integral part of this document.

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, 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;
- inclusion 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 and the essential requirements of Directive 2014/68/EU on Pressure Equipment aimed to be covered [OJEC L 189];
- inclusion of Annex ZB on the Relationship between this European Standard and the essential requirements of Directive 93/42/EEC on medical devices aimed to be covered [OJEC L 169].

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Introduction

EN 14222 is referred to normatively in EN 285:2015 '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 and EN 13060:2014+A1:2018.

This document refers to EN 12953, *Shell boilers* and EN 13445, *Unfired pressure vessels*.

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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 285:2015¹⁾, *Sterilisation — Steam sterilizers — Large sterilizers*

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 12953-6:2011, *Shell boilers — Part 6: Requirements for equipment for the boiler*

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

EN 12953-9:2007, *Shell boilers — Part 9: Requirements for limiting devices of the boiler and accessories*

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

EN 13445-2:2014²⁾, *Unfired pressure vessels — Part 2: Materials*

EN 13445-3:2014²⁾, *Unfired pressure vessels — Part 3: Design*

EN 13445-4:2014²⁾, *Unfired pressure vessels — Part 4: Fabrication*

EN 13445-5:2014²⁾, *Unfired pressure vessels — Part 5: Inspection and testing*

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

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

EN 61010-1:2010³⁾, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements (IEC 61010-1:2010)*

1) This document is being amended by EN 285:2015/FprA1:2020.

2) Including all amendments.

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

EN 61010-2-040:2015, *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 61010-2-040:2015)*

EN 62061:2005⁴⁾, *Safety of machinery — Functional safety of safety-related electrical, electronic and programmable electronic control systems (IEC 62061:2005)*

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

EN ISO 13849-1:2015, *Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design (ISO 13849-1:2015)*

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 12953-6:2011, 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 terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://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, limiters) (see also Figure 1). If this is achieved by multi channel systems, then all items or limiters for safety purposes are included with safety (protective) system.

4) This document is impacted by amendments EN 62061:2005/A1:2013 and EN 62061:2005/A2:2015.