



SLOVENSKI STANDARD
SIST EN 14222:2021

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Nadomešča:
SIST EN 14222:2003

Parni kotli iz nerjavnega jekla

Stainless steel steam boilers

Edelstahl-Dampfkessel

Chaudières à vapeur en acier inoxydable

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Ta slovenski standard je istoveten z: EN 14222:2021

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ICS:

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EUROPEAN STANDARD

EN 14222

NORME EUROPÉENNE

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Stainless steel steam boilers

Chaudières à vapeur en acier inoxydable

Edelstahl-Dampfkessel

This European Standard was approved by CEN on 13 December 2020.

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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) 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of an identical text or by endorsement, at the latest by July 2021, and conflicting national standards shall be withdrawn at the latest by July 2021.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);

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- 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].

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, Turkey and the United Kingdom.

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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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EN 14222:2021 (E)**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 · 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.

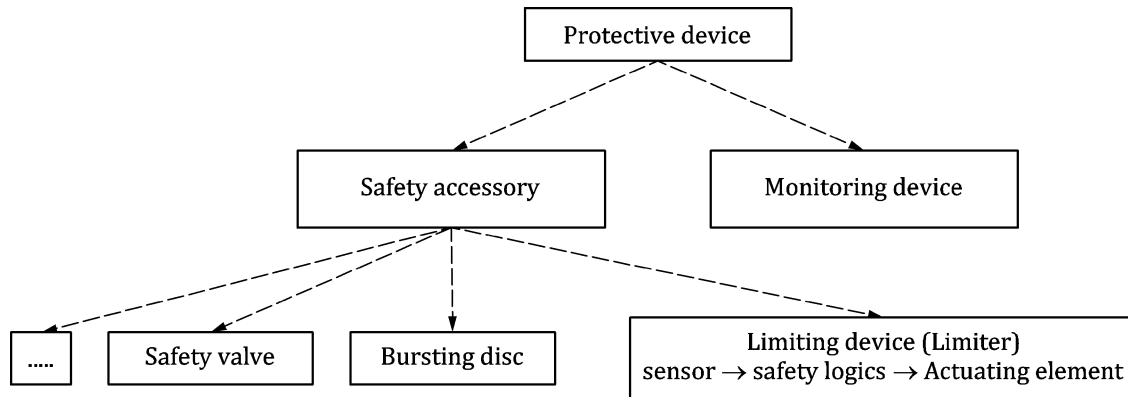


Figure 1 — Protective devices and safety accessory according to Directive 2014/68/EU (PED)

Note 2 to entry: Fixed value can e.g. be specified pressure, temperature, flow, water level.

[SOURCE: EN 12953-9:2007, 3.1 — modified, Note 2 to entry added to move examples “(e.g. pressure, temperature, flow, water level)” from the definition into a note and cited Directive has been updated in the Figure title from “Directive 97/23/EC” to “Directive 2014/68/EU”.]

3.3

lock-out

isolation of energy supply which requires a manual intervention to reinstate

3.4

functional check

testing of the safety device to ensure it performs its intended function

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3.5

steam boiler

device to supply steam for external use comprising a vessel under pressure containing water to generate the steam by applying heat energy

4 Materials

Each steam boiler shall be manufactured from austenitic steel and/or austenitic ferritic stainless steel (duplex) in accordance with EN 13445-2:2014.

5 Design

Each steam boiler shall be designed in accordance with EN 13445-3:2014.

6 Manufacture

Each steam boiler shall be manufactured in accordance with EN 13445-4:2014.

7 Inspection and testing

Each steam boiler shall be inspected, tested and documented in accordance with EN 13445-5:2014.

8 Marking

The requirements for marking shall be in accordance with EN 12953-5:2020.

9 Requirements for equipment

9.1 General

9.1.1 The requirements for electrically heated stainless steel steam boilers are given in EN 60204-1:2018. The requirements regarding shell boilers are derived from EN 12953-1:2012, EN 12953-5:2020, EN 12953-6:2011, EN 12953-8:2001 and EN 12953-9:2007 and modified by the following clauses.

9.1.2 Materials in contact with steam shall:

- a) resist attack from steam and condensate;
- b) not cause deterioration of the quality of the steam;
- c) not release any substances known to be toxic in such quantities that could create a health or environmental hazard.

NOTE For further requirements on material, see EN 285:2015, 4.2.

9.2 Safeguards against excessive pressure

Each steam boiler shall be equipped with safeguards against excessive pressure in accordance with EN 12953-8:2001. In a deviation from EN 12953-8:2001 the minimum inside diameter of the safety valve seat may be reduced to 8 mm.

9.3 Materials for valves, fittings, flanges and bolting

Steel materials for valves, fittings, flanges and bolting shall be in accordance with EN 13445-2:2014.

9.4 Limiting devices and safety circuits

9.4.1 Limiters shall be designed in accordance with EN 12953-9:2007. In addition to the requirements of EN 12953-9:2007, 5.4.2, level electrode inclinations between 45° and 90° from the vertical shall be allowed provided that functional capability and equivalent safety level examinations have proven successful.

The electrical safety circuits shall be in accordance with EN 60204-1:2018. If the steam boiler is a part of a sterilizer complying with EN 285:2015 or EN 13060:2014+A1:2018, electrical safety circuits may be analogous to the sterilizer in accordance to EN 61010-1:2010 and EN 61010-2-040:2015.

9.4.2 Software used for limiting devices, the boiler heat supply system and any further safety function and component shall be developed, verified and validated according to the respective requirements given by EN 285:2015 and EN 13060:2014+A1:2018, respectively (see EN 285:2015, 7.3 and EN 13060:2014+A1:2018, 4.5.4). Respective requirements from EN 12953-6:2011 or EN 12953-9:2007 may be applied alternatively.

9.4.3 Based on a hazard analysis, for limiting devices, the boiler heat supply system and any further safety function and component appropriate safety performance levels shall be established according to EN 62061:2005 and/or EN ISO 13849-1:2015 and EN ISO 13849-2:2012 (see EN 60204-1:2018, 9.4.1). Respective requirements from EN 12953-6:2011 or EN 12953-9:2007 may be applied alternatively.