



SLOVENSKI STANDARD

oSIST prEN 14222:2019

01-julij-2019

Mnogovodni kotli iz nerjavnega jekla

Stainless steel shell boilers

Edelstahl-Großwasserraumkessel

Chaudières à tubes de fumée en acier inoxydable

Ta slovenski standard je istoveten z: prEN 14222

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ICS:

27.060.30	Grelniki vode in prenosniki toplote	Boilers and heat exchangers
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English Version

Stainless steel shell boilers

Chaudières à tubes de fumée en acier inoxydable

Edelstahl-Großwasserraumkessel

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (prEN 14222:2019) 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 document is currently submitted to the CEN Enquiry.

This document will supersede EN 14222:2003.

This document has been prepared under a mandate (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, ZB and ZC which are integral parts of this document.

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Introduction

In 2016 CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices” adopted EN 14222 from CEN/TC 269 “Shell and water-tube boilers” into its work programme. The main reason was the need for CEN/TC 102 to revise EN 14222:2003, as e.g. EN 285 and EN 13060 refer to it and comments submitted by CEN/TC 102 during systematic review in 2014 could not be reviewed by CEN.

EN 14222 is to a large extent referred to normatively in EN 285:2015 ‘Sterilization – Steam sterilizers – Large sterilizers’ and EN 13060:2014+A1:2018 ‘Small steam sterilizers’, two standards developed by CEN/TC 102 ‘Sterilizers for medical purposes’.

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.

However, due to a lack of relevant expertise able to engage in a revision process for EN 14222:2003, CEN/TC 269 could not take the CEN/TC 102 comments into account but recognized that a revision would be necessary.

It is essential that the revised standard supports listing of those sterilizer standards of CEN/TC 102 (e.g. EN 285, EN 13060) in the European Journal, which are referencing normatively to EN 14222.

The standard covers electrically heated shell boilers specifically dedicated for generating steam for sterilizers and disinfectors.

This European Standard 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 shell boilers manufactured from stainless steel specifically dedicated for generating steam for sterilizers and disinfectors.

This document covers only 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, *Sterilization — Steam sterilizers — Large sterilizers*

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

EN 12953-5:2002, *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 13445-2:2014, *Unfired pressure vessels — Part 2: Materials*

EN 13445-3:2014, *Unfired pressure vessels — Part 3: Design*

EN 13445-4:2014, *Unfired pressure vessels — Part 4: Fabrication*

EN 13445-5:2014, *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 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements (IEC 61010-1:2010, modified)*

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)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 12953-1:2012, EN 12953-6:2011 and the following apply.

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

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

3.1**control**

regulation of variables within specified limits

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

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

3.2**limiter**

device that, on reaching a fixed value (e.g. pressure, temperature, flow, water level) is used to interrupt and lock-out the heating energy supply and lock-out requires manual unlocking before restart

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

4 Materials

Each steam boiler shall be manufactured from austentic steel and/or austentic 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 12953-5:2002.

9 Requirements for equipment**9.1 General**

The following requirements for equipment for electrically heated stainless steel shell boilers are worked out on the basis of EN 12953-6:2011.

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 could 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 addition to EN 12953-9:2007. In accordance with EN 12953-9:2007, 5.4.2 level electrode inclinations between 45° and 90° from the vertical shall be allowed provided that functional capability 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 or EN 13060, 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 Functional checking of all limiters shall be possible at any time during operation or by a separate test, e.g. by simulation, where appropriate.

9.4.3 If a limiter responds, the boiler shall automatically go to a safe condition and a signal shall be given to indicate boiler malfunction.

9.4.4 After manual resetting of a limiter lock-out, the boiler shall be put back into operation by manual intervention only.

9.5 Boiler heat supply

9.5.1 The pressure of each boiler shall be controlled automatically by regulating the heating energy input. If the steam boiler is a part of a sterilizer complying with EN 285:2015 or EN 13060:2014+A1:2018, control of the steam boiler may be executed by the sterilizer's control equipment as specified in EN 285:2015, Clause 7, or EN 13060:2014+A1:2018, 4.5.

9.5.2 Automatic start-up of the boiler and the system is permitted provided that equipment is installed to ensure that start-up is conducted safely. Automatic restarting after normal shut-down shall not be considered a start-up.

9.5.3 A high temperature alarm device for shutting off the heating energy supply shall be provided. The alarm temperature shall be determined by the manufacturer.

9.5.4 The electrical supply circuits and the safety of the control equipment shall conform to 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, the electrical supply circuits and the safety of the control equipment may be analogous to the sterilizer in accordance to EN 61010-1:2010 and EN 61010-2-040:2015.

9.6 Water level indication

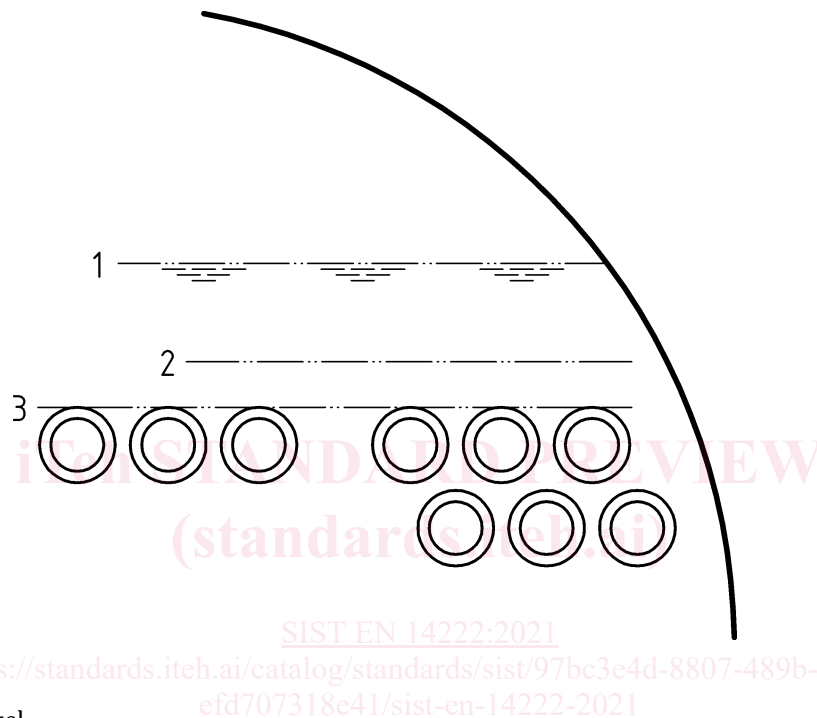
9.6.1 Each steam boiler shall have at least one independent means (independent from other equipment) of indicating the water level, which shall be a gauge of transparent material directly connected to the boiler shell.

9.6.2 The gauge(s) shall be mounted so that the water level is visible through the transparent material at the lowest alarm level, i.e. at the lowest permissible water level (LWL), which shall be

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marked. The maximum permissible water level, which shall be specified by the boiler manufacturer, shall be visible. The gauge shall be capable of showing a measurement of "15 mm below LWL".

9.6.3 If the steam generator is equipped with a safety water level limiter (see 9.12.1) then the lowest permissible water level (LWL) of the boiler (see Figure 1), which shall be permanently and legibly marked on the boiler shell and identified by the letters "LWL", shall be at least 30 mm above the uppermost surface of the immersion heaters "HHS". If the steam boiler is equipped with a safety temperature limiter instead of a water level limiter (see 9.12.1), the lowest permissible water level (LWL) shall be marked at the switch point of the safety temperature limiter.

**Key**

- 1 controlled water level
- 2 lowest permissible water level (LWL)
- 3 uppermost surface of the immersion heaters (HHS)

Figure 1 — Water level indication

9.6.4 Pipes and fittings connecting a water level gauge to a boiler shall be as short as possible and constructed so that no undrained pocket is formed between the boiler and the gauge. There shall be no outlet therefrom except for regulators, steam pressure gauges and drains or other similar apparatus, which does not permit the escape of a significant amount of steam.

Pipes connecting a water level gauge to the boiler shall not be less than 8 mm bore. Where a chamber of a safety control or alarm device is fitted to the water gauge or its piping, the connecting pipes between the boiler and the water level gauge shall have a bore not less than 15 mm.

9.6.5 Where the water level gauge is a part of the boiler shell, the requirements of 9.6.4 shall not apply.

9.7 Steam pressure indication

9.7.1 Each boiler shall have a steam pressure gauge in accordance with EN 285:2015, 6.2, or EN 13060:2014+A1:2018, 4.4.2.4, for small steam sterilizers connected to the steam space either directly or through the water level gauge column or its steam connection.

9.7.2 The steam pressure gauge shall be connected to a siphon or similar device of sufficient capacity to keep the gauge tube filled with water. The pipe shall be of sufficient size and shall have provision for blowing through if possible. Alternatively, the pressure line shall be fitted with an isolating membrane close to the boiler. The pressure line between the membrane and the gauge shall contain a non-compressible fluid.

9.7.3 Steam pressure gauge connections shall be made suitable for the design working pressure of the boiler.

9.7.4 Pressure gauges shall be graduated to indicate the pressure in bars. The maximum allowable pressure shall be indicated by a fixed and readily visible red mark on the pressure gauge.

NOTE In addition, the operating pressure and the safety valve set pressure can also be indicated.

9.7.5 Each boiler shall be provided with a valve connection for the special purpose of connecting a test gauge when the boiler is in service so that the accuracy of the boiler steam gauge can be ascertained.

9.8 Drain and blowdown devices

9.8.1 Each boiler shall be fitted with drain valves placed at, or as near as practicable to, the lowest point of the apparatus.

NOTE On some boilers, drain valves can be used for blowdown purposes.

9.8.2 Where drain valves from two or more boilers are connected to a common discharge, two valves shall be fitted to each drain line, one being of a non-return type to prevent the contents of one boiler passing to another. As an alternative to the non-return valves an interlock system, enabling only one valve to be open at a time shall be allowed.

9.8.3 Taper-plug valves where fitted, shall be of the bolted cover type with separately packed glands.

9.8.4 Where drain valves are not self-closing or capable of being locked in the closed position, a further shut-off device shall be installed in the line.

NOTE Having the drain valve enclosed by a cabinet or an inspection door is included in the term "being locked in a closed position".

9.9 Valves for connections

9.9.1 Steam outlets

The stop valve connecting the boiler to the steam pipe shall be attached directly to the boiler or shall be as near to it as practicable. The valve should preferably be of a type, which positively indicates whether it is open or closed. Where more than one boiler is connected to a common header or steam manifold, the steam connections for each boiler shall be provided with two stop valves or some similar safety method shall be provided.

NOTE It is preferable that the valve nearest the boiler be a non-return type.

9.9.2 Feed connections

Each feed pipe to any boiler shall be provided with a non-return valve and a separate stop valve near the boiler.