



SLOVENSKI STANDARD
SIST EN 285:2016/oprA1:2018
01-december-2018

Sterilizacija - Parni sterilizatorji - Veliki sterilizatorji

Sterilization - Steam sterilizers - Large sterilizers

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Ta slovenski standard je istoveten z: EN 285:2015/prA1:2018

[SIST EN 285:2016/kpra1:2020](https://standards.iteh.ai/catalog/standards/sist/02e61d7c-bf9d-4bf0-8b21-e0c96bff22f0/sist-en-285-2016-kpra1-2020)

<https://standards.iteh.ai/catalog/standards/sist/02e61d7c-bf9d-4bf0-8b21-e0c96bff22f0/sist-en-285-2016-kpra1-2020>

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

SIST EN 285:2016/oprA1:2018 **en,fr,de**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
EN 285:2015
prA1

September 2018

ICS 11.080.10

English Version

Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

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

This draft amendment A1, if approved, will modify the European Standard EN 285:2015. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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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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
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 285:2015/prA1:2018) 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 has been prepared under a mandate 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 Annex ZA, which is an integral part of EN 285:2015.

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EN 285:2015/prA1:2018 (E)**1 Modification to Clause 3, Terms and definitions**

Add the text below about steam as a Note 1 to entry to the terms 3.17 and 3.27:

"Note 1 to entry: The requirements for steam penetration and the definition of "saturated steam" are currently points for discussion in both CEN/TC 102/WG 5 and in ISO/TC 198/WG 3, which is the international working group that deals with the closely related EN ISO 17665-series."

2 Modification to 6.2, Measuring system

Change in 6.2 the last paragraph to become a Note 3, and add cross-reference h) to read:

"NOTE 3 For the purpose of g) and h) absolute pressure transducers can be used providing the offset from ambient pressure is considered."

3 Modification to 6.4.4, Pressure measuring chains for control, recording and indication

Add after the headline of 6.4.4 the following new sub-clause headlined:

"6.4.4.1 Chamber pressure measuring chains"**4 Addition of a new sub-clause 6.4.4.2**

Add after sub-clause 6.4.4.1 the following new sub-clause:

"6.4.4.2 Jacket and steam supply measuring chains"

Pressure measuring chains shall:

- a) indicate in kilopascals or bars; [SIST EN 285:2016/kprA1:2020](https://standards.iteh.ai/catalog/standards/sist/02e61d7c-bf9d-4bf0-8b21-11e9-7712-8519e4014040)
- b) have an accuracy of $\pm 1,6$ % or better over the scale range 0 kPa to 400 kPa; <https://standards.iteh.ai/catalog/standards/sist/02e61d7c-bf9d-4bf0-8b21-11e9-7712-8519e4014040>
- c) be graduated in divisions not greater than 20 kPa;
- d) have means to adjust *in situ* without dismantling the instrument."

5 Modification to 8.1.3

Add the text below about steam as NOTE 4 to 8.1.3:

"NOTE 4 The requirements for steam penetration and the definition of "saturated steam" are currently points for discussion in both CEN/TC 102/WG 5 and in ISO/TC 198/WG 3, which is the international working group that deals with the closely related EN ISO 17665-series."

6 Modification to 15.1, General

Add the text below about steam as NOTE 2 to 15.1:

"NOTE 2 The requirements for steam penetration and the definition of "saturated steam" are currently points for discussion in both CEN/TC 102/WG 5 and in ISO/TC 198/WG 3, which is the international working group that deals with the closely related EN ISO 17665-series."

Renumber the first NOTE into "NOTE 1".