

SLOVENSKI STANDARD SIST EN 13060:2005/oprA2:2009

01-april-2009

Mali parni sterilizatorji

Small steam sterilizers

Dampf-Klein-Sterilisatoren

Petits stérilisateurs à la vapeur d'eau

Ta slovenski standard je istoveten z: EN 13060:2004/prA2

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

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English Version

Small steam sterilizers

Petits stérilisateurs à la vapeur d'eau

Dampf-Klein-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 A2, if approved, will modify the European Standard EN 13060:2004. 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.

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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

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Foreword

This document (EN 13060:2004/prA2:2009) has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", 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 EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA, B, C or D, which is an integral part of this document.

1 Addition in Foreword

Add before the last subclause :

"The performance requirements specified in this document are not intended for the process to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jakob disease. However, some national regulations require the use of modified steam processes as part of a general prion decontamination programme."

2 Modification concerning the whole standard

Modify all occurrences of "residual air" to "non-condensable gases" in the document.

3 Modification to clause 3

Add the following definitions:

3.18

non-condensable gas

air and other gas which will not condense under the conditions of steam sterilization

and amend the ongoing numbering.

Replace in 3.24:

"[EN 764-1:2004, definition 4.9]" by "[EN 764-1:2004, definition 3.8]"

3.24

maximum allowable pressure

maximum pressure for which the equipment is designed as specified by the manufacturer

[EN 764-1:2004, definition 3.8]

Delete in 3.24 "Note 1 The maximum allowable pressure is specified by the manufacturer for a specific location. This is the location of connection of protective and/or limiting devices or the top of equipment or if not appropriate any other point specified"

keep only note 2 and renumber note

Replace in 3.27:

"[EN 764-1:2004, definition 4.8]" by "[EN 764-1:2004, definition 3.6]"

3.27

operating pressure

fluid pressure occurring during specified operating conditions

[EN 764:2004, definition 3.6]

and keep the corresponding note

4 Modification of 4.7.3.2

In item a), replace the sentence by:

"the reservoir and associated pipe work shall be fitted with a valve or other device to allow draining by the operator or the automatic control system";

5 Addition of 8.11

Add the following note at the end of the text:

"NOTE If necessary, the indicator may be slightly curved but not folded to allow fitting into the 5 mm inner diameter for a) and b)."