

SLOVENSKI STANDARD SIST EN 13060:2015/oprA1:2018

01-januar-2018

Mali parni sterilizatorji

Small steam sterilizers

Dampf-Klein-Sterilisatoren

Petits stérilisateurs à la vapeur d'eau

Ta slovenski standard je istoveten z: EN 13060:2014/prA1:2017

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM DRAFT EN 13060:2014

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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 A1, if approved, will modify the European Standard EN 13060:2014. 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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SIST EN 13060:2015/oprA1:2018

EN 13060:2014/prA1:2017 (E)

Contents

Europe	ean forewordean	3
1	Modification to Introduction	4
2	Modification to 5.3.1	4

EN 13060:2014/prA1:2017 (E)

European foreword

This document (EN 13060:2014/prA1:2017) 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 13060:2014.

EN 13060:2014/prA1:2017 (E)

1 Modification to Introduction

Add to introduction before last paragraph the following new paragraph:

"For sterilizer models of a given design, that have been supplied to the market prior to publication of this edition of EN 13060, with the 4 K band as specified by EN 13060:2004+A2:2010, 5.3.2, these sterilizers can continue to be supplied to the market with the 4 K band."

2 Modification to 5.3.1

Delete in 5.3.1, after second list item:

"For products designed and placed on the market prior to publication of this edition of EN 13060 the 4 K band as specified by EN 13060:2004+A2:2010, 5.3.2, may apply."

Add the following note under the current note in 5.3.1 and number both notes:

"NOTE 2 For sterilizer models of a given design, that have been supplied to the market prior to publication of this edition of EN 13060, with the 4 K band as specified by EN 13060:2004+A2:2010, 5.3.2, these sterilizers can continue to be supplied to the market with the 4 K band."