SLOVENSKI STANDARD
SIST EN 1422:2000/kprA1:2009

01-marec-2009

Sterilizatorji za uporabo v medicini - Sterilizatorji z etilenoksidom - Zahteve in preskusne metode

Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods

Sterilisatoren für medizinische Zwecke - Ethylenoxid-Sterilisatoren - Anforderungen und Prüfverfahren

Stérilisateurs à usage médical - Stérilisateurs à l'oxyde d'éthylène - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: **EN 1422:1997/prA1**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

SIST EN 1422:2000/kprA1:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 1422:1997

prA1

December 2008

ICS 11.080.10

English Version

Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods

Stérilisateurs à usage médical - Stérilisateurs à l'oxyde d'éthylène - Exigences et méthodes d'essai

Sterilisatoren für medizinische Zwecke - Ethylenoxid-Sterilisatoren - Anforderungen und Prüfverfahren

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

This draft amendment A1, if approved, will modify the European Standard EN 1422:1997. 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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN 1422:1997/prA1:2008: E

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Foreword

This document (EN 1422:1997/prA1:2008) 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 Unique Acceptance Procedure.

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, which is an integral part of this document.

1 Modifications to Annex ZA

Delete the title of Annex ZA and substitute the following:

"Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC".

Delete the introductory text to Table ZA and substitute the following:

"This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations."

Delete Title of Table ZA and substitute the following:

"Table ZA.1 - Correspondence between this European Standard and Directive 93/42/EEC on medical devices".

Changes to existing table ZA:

Where Essential Requirement 12 is listed, amend to read "12 [except 12.1a)]".

Where Essential Requirement 13 is listed, amend to read "13 [except 13.6q)]" *and add to column "Comments"* "The relevant Essential Requirement 13.3 a) is partly addressed."

Add the following rows to Table ZA:

"

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
17	12.1a)	This relevant Essential Requirement is partially addressed in this European Standard
18	13.3 a)	This relevant Essential Requirement is partly addressed in this European Standard
-	13.6 q)	This relevant Essential Requirement is not addressed in this European Standard

"

Add the following after Table ZA:

"WARNING – Other requirements and other EU-directives may be applicable to the product(s) falling within the scope of the standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	**Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC**	**Qualifying remarks/Notes**
6, 7, 19	1.1.3	This relevant EHSR is partly addressed in this Standard
	1.1.4	This relevant EHSR is not addressed in this Standard
	1.1.5	This relevant EHSR is not addressed in this Standard
14, 17	1.1.6	This relevant EHSR is partly addressed in this Standard
15, 17	1.1.7	
14, 19	1.2.1	This relevant EHSR is partly addressed in this Standard
14	1.2.2	
14	1.2.3	
14	1.2.4	1.2.4.3 is not fully covered.
14	1.2.5	
14, 19	1.2.6	This relevant EHSR is partly addressed in this Standard
19	1.3.1	This relevant EHSR is partly addressed in this Standard
4, 19	1.3.2	
19	1.3.3	
19	1.3.4	
19	1.3.7	This relevant EHSR is partly addressed in this Standard
19	1.3.8.1	This relevant EHSR is partly addressed in this Standard
19	1.3.8.2	This relevant EHSR is partly addressed in this Standard
19	1.3.9	

Table ZA.2 *(continued)*

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
	1.4.1	This relevant EHSR is not addressed in this Standard
	1.4.2	This relevant EHSR is not addressed in this Standard
	1.4.3	This relevant EHSR is not addressed in this Standard
19	1.5.1	
	1.5.2	This relevant EHSR is not addressed in this Standard
19	1.5.3	
19	1.5.4	This relevant EHSR is partly addressed in this Standard
19	1.5.5	
19	1.5.6	
11, 19	1.5.8	
	1.5.9	This relevant EHSR is not addressed in this Standard
6, 7, 10, 19	1.5.13	
8, 17, 19	1.5.14	
17, 19	1.6.1	This relevant EHSR is partly addressed in this Standard
8, 14, 17, 19	1.6.2	
19	1.6.3	
8, 14	1.6.4	
7, 8, 10	1.6.5	This relevant EHSR is partly addressed in this Standard
14, 19	1.7.1	This relevant EHSR is partly addressed in this Standard
14, 17	1.7.2	This relevant EHSR is partly addressed in this Standard
18	1.7.3	This relevant EHSR is partly addressed in this Standard
17	1.7.4	This relevant EHSR is partly addressed in this Standard

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