



SLOVENSKI STANDARD
SIST EN 14180:2003/kprA1:2009
01-marec-2009

Sterilizatorji za uporabo v medicini - Sterilizatorji s paro nizke temperature in s formaldehidom - Zahteve in preskušanje

Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

Sterilisatoren für medizinische Zwecke - Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren - Anforderungen und Prüfung

Stérilisateur à usage médical - Stérilisateur à la vapeur et au formaldéhyde à basse température - Exigences et essais

Ta slovenski standard je istoveten z: EN 14180:2003/prA1

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

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EUROPEAN STANDARD
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English Version

Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

Stérilisateurs à usage médical - Stérilisateurs à la vapeur et au formaldéhyde à basse température - Exigences et essais

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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 14180:2003. 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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Foreword

This document (EN 14180:2003/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.

EN 14180:2003/prA1:2008 (E)

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 first four paragraphs 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.1 and substitute the following:

"Correspondence between this European Standard and Directive 93/42/EEC on medical devices"

Changes to existing table ZA.1:

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.1:

"

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard
9	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.1:

"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."

Add the following Table ZA.2:

"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
4	1.1.3	
4	1.1.4	This relevant EHSR is partially addressed in this Standard
9	1.1.5	This relevant EHSR is partly addressed in this Standard
5, 9	1.1.6	This relevant EHSR is partly addressed in this Standard
6, 9, 10	1.1.7	
4, 5,	1.2.1	This relevant EHSR is partly addressed in this Standard
4, 5, 9	1.2.2	
4, 5, 9	1.2.3	
4, 5, 9	1.2.4	
4, 5	1.2.5	
4, 5	1.2.6	This relevant EHSR is partly addressed in this Standard
4	1.3.1	This relevant EHSR is partly addressed in this Standard
4	1.3.2	
4	1.3.3	
4	1.3.4	
4	1.3.7	This relevant EHSR is partly addressed in this Standard
4	1.3.8.1	This relevant EHSR is partly addressed in this Standard
4	1.3.8.2	
4	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
4	1.5.1	
4	1.5.2	
4	1.5.3	
4	1.5.4	This relevant EHSR is partly addressed in this Standard
4	1.5.5	
4	1.5.6	
4	1.5.7	
4	1.5.8	
	1.5.9	This relevant EHSR is not addressed in this Standard
4, 5	1.5.13	
4, 5, 9	1.5.14	
4, 9	1.6.1	This relevant EHSR is partly addressed in this Standard
4, 9	1.6.2	
4	1.6.3	
5	1.6.4	
9	1.6.5	
4, 5, 9	1.7.1	This relevant EHSR is partly addressed in this Standard
9	1.7.2	This relevant EHSR is partly addressed in this Standard
8	1.7.3	This relevant EHSR is partly addressed in this Standard
9	1.7.4	This relevant EHSR is partly addressed in this Standard

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