



**SLOVENSKI STANDARD**  
**SIST EN 285:2006/kprA2:2009**  
**01-marec-2009**

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**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 285:2006/prA2**

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**ICS:**

11.080.10 Sterilizacijska oprema Sterilizing equipment

**SIST EN 285:2006/kprA2:2009 en,fr**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
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**FINAL DRAFT**  
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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 unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 102.

This draft amendment A2, if approved, will modify the European Standard EN 285:2006. 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  
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## Foreword

This document (EN 285:2006/prA2:2008) 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 285:2006/prA2:2008 (E)****1 Modifications to Table A.1**

In column "stage A", rows 1, 2, 5 and 7, replace "Table D.1" with "Table E.1".

In column "stage C", row 4, replace "5.2.4" with "5.2.2.2".

In column "stage C", rows 5 and 7, replace "Table D.1" with "Table E.1".

**2 Modifications to 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 the following to column "Qualifying remarks/Notes":

"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
12.2, 26.3 g)	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:

"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)**

<b>Clause(s)/sub-clause(s) of this EN</b>	<b>Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC</b>	<b>Qualifying remarks/Notes</b>
4.2, 11, 13, Annex B, Annex C, Annex E	1.1.3	This relevant EHSR is addressed in this Standard
	1.1.4	This relevant EHSR is not addressed in this Standard
11, 26.2 a)	1.1.5	This relevant EHSR is partly addressed in this Standard
6, 6.1.1.2, 6.3, 7.1.1, 11	1.1.6	This relevant EHSR is partly addressed in this Standard
11	1.1.7	This relevant EHSR is addressed in this Standard
7, 7.1.1, 7.1.6, 7.1.8, 7.1.9, 7.1.10, 7.1.12, 7.2, 11	1.2.1	This relevant EHSR is partly addressed in this Standard
4.3.2.4, 6.1.1.2, 11	1.2.2	This relevant EHSR is addressed in this Standard
11, 14, Annex F	1.2.3	This relevant EHSR is addressed in this Standard
11	1.2.4	This relevant EHSR is addressed in this Standard
7.1.5, 7.1.9, 11, 26.3	1.2.5	This relevant EHSR is addressed in this Standard
11, 13.2	1.2.6	This relevant EHSR is partly addressed in this Standard
4.4, 11, 26.2, 26.3 j), Annex E	1.3.1	This relevant EHSR is partly addressed in this Standard
4.2, 4.4, 5.1, 11, 26.3	1.3.2	This relevant EHSR is addressed in this Standard
11	1.3.3	This relevant EHSR is addressed in this Standard
11	1.3.4	This relevant EHSR is addressed in this Standard
4.4, 11	1.3.7	This relevant EHSR is partly addressed in this Standard

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
4.4.2, 11, 26.3 f)	1.3.8.1	This relevant EHSR is partly addressed in this Standard
11, 26.2 o)	1.3.8.2	This relevant EHSR is partly addressed in this Standard
	1.3.9	This relevant EHSR is not addressed in this Standard
	1.4.1	This relevant EHSR is not addressed in this Standard
	1.4.2	This relevant EHSR is not addressed in this Standard
4.3.1, 11, 26.3 b)	1.4.3	This relevant EHSR is partly addressed in this Standard
11	1.5.1	This relevant EHSR is addressed in this Standard
11	1.5.2	This relevant EHSR is addressed in this Standard
5.1, 11	1.5.3	This relevant EHSR is addressed in this Standard
4, 5, 11, 13, 26.2, 26.3, Annex E	1.5.4	This relevant EHSR is partly addressed in this Standard
4.3.4, 5.1.2, 11	1.5.5	This relevant EHSR is addressed in this Standard
4, 5, 11, 26.3	1.5.6	This relevant EHSR is addressed in this Standard
9, 11	1.5.8	This relevant EHSR is addressed in this Standard
	1.5.9	This relevant EHSR is not addressed in this Standard
11	1.5.13	This relevant EHSR is addressed in this Standard
11	1.5.14	This relevant EHSR is addressed in this Standard
7.1.8, 7.1.9, 11, 26.3 b), 26.3 g)	1.6.1	This relevant EHSR is partly addressed in this Standard.