SLOVENSKI STANDARD
SIST EN 1782:2000/kprA1:2009

01-april-2009

Sapniļ ni (endotrahealni) tubusi in priključ ki

Tracheal tubes and connectors

Trachealtuben und Verbindungsstücke

Tubes trachéaux et raccords

Ta slovenski standard je istoveten z: **EN 1782:1998/prA1**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN 1782:2000/kprA1:2009 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 1782:1998

prA1

January 2009

ICS 11.040.10

English Version

Tracheal tubes and connectors

Tubes trachéaux et raccords

Trachealtuben und Verbindungsstücke

This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 215.

This draft amendment A1, if approved, will modify the European Standard EN 1782:1998. 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 1782:1998/prA1:2009: E

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Foreword

This document (EN 1782:1998/prA1:2009) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

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 Modification to 4.3

Add the following to 4.3:

"If phthalates are incorporated in parts of the medical devices coming directly or indirectly into contact with the patient the medical device shall be labelled accordingly.

NOTE 2 Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction."

Renumber the existing note as "Note 1".

2 Addition of subclauses 4.8 – 4.10

Insert the following new subclauses:

"4.8 Usability

The manufacturer shall address in a usability engineering process the risk resulting from poor usability (see IEC 60601-1-6 and IEC 62366).

Check compliance by inspection of the usability engineering file.

4.9 Clinical evaluation

A clinical evaluation shall be performed and documented in the risk management file.

Check compliance by inspection of the risk management file.

4.10 Biophysical or modelling research

Where appropriate, validated biophysical or modelling research shall be carried out.

Check compliance by inspection of the technical file."

3 Modifications to Clause 7

Add the following to subclause 7.2.2.1 f):

“in addition, the name and address of the authorized representative if the manufacturer does not have a registered place of business in the Community;”

Add the following to subclause 7.2.2.1 h):

“NOTE 2 The attention of manufacturers is drawn to the regulation provision for a consistent use of indication for single-use devices across the Community.”

Renumber the existing Note as "Note 1".

Add the following to subclause 7.2.2.2:

“For single use devices the manufacturer shall disclose in the instructions for use or upon request the risks associated with reuse.”

4 Modifications to Annex ZA

Delete the introductory text to Table ZA.1 and substitute the following:

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

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."

Amend the column headings of Table ZA.1 to read as follows:

"

Clause(s)/sub-clause(s) of this EN	**Essential Requirements (ERs) of Directive 93/42/EEC**	**Qualifying remarks/Notes**

"

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**
4.3	7.5 (1st paragraph & 2nd paragraph)	
4.8	1 (2nd paragraph, 1st dash & 2nd dash)	
4.9	6a)	
4.10	7.1 (3rd dash)	
7.2.2.2	13.6 (h)(2nd paragraph)	
7.2.2.1 f)	13.3 (a):	
7.2.2.1 h)	13.3 (f)	

"

Add the following to follow table ZA.1:

"WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."