SLOVENSKI STANDARD
SIST EN 1282-2:2005/kprA1:2009

01-april-2009

Traheostomske cevke - 2. del: Cevke, ki se uporabljajo pri otrocih (ISO 5366-3:2001, spremenjen)

Tracheostomy tubes - Part 2: Paediatric tubes (ISO 5366-3:2001, modified)

Tracheotomietuben - Teil 2: Pädiatrische Tuben (ISO 5366-3:2001, modifiziert)

Tubes de trachéostomie - Partie 2: Tubes pédiatriques (ISO 5366-3:2001, modifiée)

Ta slovenski standard je istoveten z: **EN 1282-2:2005/prA1**

ICS:

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

SIST EN 1282-2:2005/kprA1:2009 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 1282-2:2005

prA1

January 2009

ICS 11.040.10

English Version

Tracheostomy tubes - Part 2: Paediatric tubes (ISO 5366-3:2001, modified)

Tubes de trachéostomie - Partie 2: Tubes pédiatriques (ISO 5366-3:2001, modifiée)

Tracheotomietuben - Teil 2: Pädiatrische Tuben (ISO 5366-3:2001, geändert)

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 1282-2:2005. 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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (EN 1282-2:2005/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 Clause 5

Add the following paragraphs:

"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 6.2.5 – 6.2.7

Insert the following new subclauses:

"6.2.5

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

Check compliance by inspection of the usability engineering file.

6.2.6

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

Check compliance by inspection of the risk management file.

6.2.7

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

Check compliance by inspection of the technical file."

3 Modification to 8.3.1

Add the following paragraph at the end of subclause 8.3.1:

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

4 Modification to 8.3.2 h)

Add the following paragraph at the end of 8.3.2 h):

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

5 Modification to 8.3.2 l)

Add the following paragraph at the end of 8.3.2 l):

"Note: The attention of manufacturers is drawn to consistent use of indication across the Community for single use devices."

6 Modifications to Annex ZA

Delete the introductory text to Table ZA 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 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."

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**
5	7.5 (1st paragraph)	
5	7.5 (2nd paragraph)	
6.2.5	1 (2nd paragraph, 1st dash) (2nd paragraph, 2nd dash)	
6.2.6	6a)	
6.2.7	7.1 (3rd dash)	
8.3.1	13.6 (h)(2nd paragraph)	
8.3.2 h)	13.3 (a):	
8.3.2 l)	13.3 (f)	

"