SLOVENSKI STANDARD
SIST EN 13544-3:2002/kprA1:2009

01-april-2009

Dihalna oprema za zdravljenje - 3. del: Vhodne naprave za zrak

Respiratory therapy equipment - Part 3: Air entrainment devices

Atemtherapiegeräte - Teil 3: Luftbeimischgeräte

Appareils de thérapie respiratoire - Partie 3 : Dispositifs d'entrainement d'air

Ta slovenski standard je istoveten z: **EN 13544-3:2001/prA1**

ICS:

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

SIST EN 13544-3:2002/kprA1:2009 **en,fr,de**

EUROPEAN STANDARD

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FINAL DRAFT
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January 2009

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English Version

Respiratory therapy equipment - Part 3: Air entrainment devices

Appareils de thérapie respiratoire - Partie 3 : Dispositifs d'entrainement d'air

Atemtherapiegeräte - Teil 3: Luftbeimischgeräte

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 13544-3:2001. 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.

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

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Foreword

This document (EN 13544-3:2001/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 2

Add the following references:

"EN 60601-1-6, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability*

EN 62366, *Medical devices - Application of usability engineering to medical devices*".

2 Modifications to Clause 7

Add the following to 7.1.2a):

"and the name and address of authorized representative where the manufacturer does not have a registered place of business in the European Community;"

Add the following to 7.1.2c)

"For single use devices the manufacturer shall disclose the risks associated with reusing in the instructions for use or upon request.

NOTE Manufacturer's attention is drawn to the regulation provision for a consistent use of indication for single use devices."

3 Modifications to Clause 8

Add the following to follow 8d)

"The instructions for use shall contain the date of issue or the latest revision.

e) 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. If such devices are used for the treatment of children or treatment of pregnant or nursing women, the residual risk has to be identified and stated in the instructions for use.

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

4 Addition of Clauses 9 and 10

Add the following new clauses 9 and 10:

"9 Usability

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

Check compliance by inspection of the usability engineering file.

10 Clinical evaluation

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

Check compliance by inspection of the risk management file."

5 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."

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**
9	1 (2nd paragraph, 1st dash & 2nd dash)	
10	6a	
8	7.5 (1st paragraph)	
8e)	7.5 (2nd paragraph & 3rd paragraph)	
7.1.2a)	13.3 (a):	
7.1.2c)	13.3 (f)	
7.1.2c)	13.6 (h)(2nd paragraph)	
8	13.6 (q)	

"

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."