



**SLOVENSKI STANDARD**  
**SIST EN 13544-2:2003/kprA1:2009**  
**01-april-2009**

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Respiratory therapy equipment - Part 2: Tubing and connectors

Atemtherapiegeräte - Teil 2: Schlauchsysteme und Verbindungsstücke

Equipement de thérapie respiratoire - Partie 2: Tubes et raccords

**Ta slovenski standard je istoveten z: EN 13544-2:2002/prA1**

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**ICS:**

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

**SIST EN 13544-2:2003/kprA1:2009      en,fr,de**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**FINAL DRAFT**  
**EN 13544-2:2002**

**prA1**

January 2009

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ICS 11.040.10

English Version

## Respiratory therapy equipment - Part 2: Tubing and connectors

Équipement de thérapie respiratoire - Partie 2: Tubes et raccords

Atemtherapiegeräte - Teil 2: Schlauchsysteme 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 13544-2:2002. 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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## EN 13544-2:2002/prA1:2009 (E)

Contents	Page
Foreword .....	3
1 Modifications to Clause 2 .....	4
2 Modification to 5.1 .....	4
3 Modifications to Clause 6 .....	4
4 Addition of Clauses 8 and 9 .....	4
5 Modifications to Annex ZA .....	5

## Foreword

This document (EN 13544-2:2002/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.

**EN 13544-2:2002/prA1:2009 (E)****1 Modifications 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 Modification to 5.1**

*Add the following:*

"d) 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."

**3 Modifications to Clause 6**

*Add the following to 1<sup>st</sup> dash item:*

"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 2<sup>nd</sup> dash item:*

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

*Add the following to 8<sup>th</sup> dash item:*

"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."

**4 Addition of Clauses 8 and 9**

*Add the following new Clauses 8 and 9:*

**"8 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.

**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."

## 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
8	1 (2 <sup>nd</sup> paragraph, 1 <sup>st</sup> dash & 2 <sup>nd</sup> dash)	
9	6a	
5.1d)	7.5 (1 <sup>st</sup> paragraph, 2 <sup>nd</sup> paragraph & 3 <sup>rd</sup> paragraph)	
6 [1 <sup>st</sup> dash]	13.3 (a):	
6 [8 <sup>th</sup> dash]	13.3 (f)	
6 [8 <sup>th</sup> dash]	13.6 (h)(2 <sup>nd</sup> paragraph)	
6 [2 <sup>nd</sup> dash]	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."