SLOVENSKI STANDARD
SIST EN 13544-1:2007/kprA1:2009

01-april-2009

Dihalna oprema za zdravljenje - 1. del: Razprševalni sistemi in njihovi sestavni deli

Respiratory therapy equipment - Part 1: Nebulizing systems and their components

Atemtherapiegeräte - Teil 1: Verneblersysteme und deren Bauteile

Matériel respiratoire thérapeutique - Partie 1: Systèmes de nébulisation et leurs composants

Ta slovenski standard je istoveten z: **EN 13544-1:2007/prA1**

ICS:

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

SIST EN 13544-1:2007/kprA1:2009 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 13544-1:2007

prA1

January 2009

ICS 11.040.10

English Version

Respiratory therapy equipment - Part 1: Nebulizing systems and their components

Matériel respiratoire thérapeutique - Partie 1: Systèmes de nébulisation et leurs composants

Atemtherapiegeräte - Teil 1: Verneblersysteme und deren Bauteile

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 13544-1:2007. 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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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

Contents

Page

Foreword

This document (EN 13544-1:2007/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 EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

1 Modification to Clause 2

In the title of reference EN 980, replace "Graphical symbols" *with* "Symbols".

In the title of reference EN 1041, replace "with" *with* "of".

In the title of reference EN 60601-1-2, replace "(IEC 60601-1-2:2001)" with "(IEC 60601-1-2:2007, modified)".

Add the following references to Clause 2:

"EN 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability (IEC 60601-1-6:2006)" and*

EN 62304, *Medical device software — Software life-cycle processes (IEC 62304:2006)*

EN 62366, *Medical devices — Application of usability engineering to medical devices (IEC 62366:2007)*".

In the title of reference EN ISO 7396-1, replace "(ISO 7396-1:2006)" with "(ISO 7396-1:2007)".

In the title of reference EN ISO 8185, replace "(ISO 8185:1997)" with "(ISO 8185:2007)".

In the title of reference EN ISO 14971, replace "(ISO 14971:2000)" with "(ISO 14971:2007)".

2 Modification to 4.1

Add the following to 4.1:

"In 3.10 Clinical evaluation add the following:

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

Check compliance by inspection of the risk management file.".

3 Modification to 6.1

Replace the addition to 6.1 e) with the following:

"The name or trademark and address of the manufacturer. For devices imported into the European Union the following applies: the name and address of the person responsible and of the authorised representative of the manufacturer established within the European Community shall be provided with the device or with the accompanying document.".

Add the following to 6.1 cc), 5th dash

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

"NOTE 1 Manufacturers' attention is drawn to the regulatory provision requiring that the indication of single use must be consistent across the Community.”.

and replace "NOTE" *after the 8th indent with* "NOTE 2".

4 Modification to 6.8.2

Add the following to 6.8.2:

"hh) Medical software

For medical devices which incorporate software or which are medical software in themselves, the software development process shall comply with EN 62304.".

Add the following to 6.8.2:

"ii) Phthalates

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.".

Add the following to 6.8.2

"jj) Date of issue

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

5 Modification to Clause 48

Add the following to Clause 48:

"NOTE Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction. See also 6.8.2 ii).".

6 Modification to Clause 54

Add the following to Clause 54

"**54.103 Usability**

The manufacturer shall address in a usability engineering process the risk resulting from poor usability according to EN 60601-1-6 and EN 62366.

Check compliance by inspection of the usability engineering file.".

7 Modification to Annex ZA

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
"54.103	1 (2nd paragraph, 1st dash)	
54.103	1 (2nd paragraph, 2nd dash)	
4.1 (3.10)	6 a)	
48	7.5 (1st paragraph)	
6.8.2 ii)	7.5 (2nd paragraph)	
6.8.2 ii)	7.5 (3rd paragraph)	
6.8.2 hh)	12.1 a)	
6.1 e)	13.3 (a)	
6.1 cc) 5th dash	13.3 (f)	
6.1 cc) 5th dash	13.6 (h) (3rd paragraph)	
6.8.2 jj)	13.6 (q)	"

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: "