SLOVENSKI STANDARD
SIST EN 794-3:2000/kprA2:2009

01-april-2009

Pljuļ ni ventilatorji - 3. del: Posebne zahteve za ventilatorje za nujno medicinsko pomoļ in prevoz

Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators

Lungenbeatmungsgeräte - Teil 3: Besondere Anforderungen an Notfall- und Transportbeatmungsgeräte

Ventilateurs pulmonaires - Partie 3: Règles particulières pour les ventilateurs d'urgence et de transport

Ta slovenski standard je istoveten z: **EN 794-3:1998/prA2**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.160	Prva pomoļ	First aid

SIST EN 794-3:2000/kprA2:2009 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

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FINAL DRAFT
EN 794-3:1998

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ICS 11.040.10; 11.160

English Version

Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators

Ventilateurs pulmonaires - Partie 3: Règles particulières pour les ventilateurs d'urgence et de transport

Lungenbeatmungsgeräte - Teil 3: Besondere Anforderungen an Notfall- und Transportbeatmungsgeräte

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 A2, if approved, will modify the European Standard EN 794-3:1998. 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

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

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Foreword

This document (EN 794-3:1998/prA2:2009) 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 62304, *Medical device software - Software life-cycle processes*

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

2 Modification to 4.1

Add the following to clause 4.1:

"3.10 Clinical evaluation

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

Check compliance by inspection of the risk management file."

3 Modifications to Clause 6

Replace 6.1dd), 2nd dash with the following:

"The name or trade name and address of the manufacturer and the name and address of authorized representative. For attachments imported into the community, 6.1e) of this European Standard applies where the manufacturer does not have a registered place of business in the Community."

Add the following to 6.1dd), 7th dash:

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

Add the following note to 6.1dd), 7th dash and renumber the existing note as 'Note 1':

"NOTE 2 Manufacturer's attention is drawn to the regulatory provision for a consistent use of indication for single use devices."

Add the following new dash item to 6.1dd):

"— 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 6.8.2bb):

"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:

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

4 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 final dash item of 6.1dd)."

5 Modification to Clause 54

Add the following to clause 54:

"54.104 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."

6 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
54.104	1 (2nd paragraph, 1st dash & 2nd dash))	
4.1 (3.10)	6a)	
48	7.5 (1st paragraph)	
6.1dd), 48	7.5 (2nd paragraph & 3rd paragraph)	
6.8.2bb)	12.1a)	
6.1dd) 2nd dash	13.3 (a):	
6.1dd) 7th dash	13.3 (f)	
6.1dd) 7th dash	13.6 (h)(2nd paragraph)	
6.8.2cc)	13.6 (q)	

"

Add the following text below Table ZA.1:

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

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."