SLOVENSKI STANDARD
SIST EN 1820:2005/kprA1:2009

01-april-2009

Dihalni baloni (ISO 5362:2000, spremenjen)

Anaesthetic reservoir bags (ISO 5362:2000, modified)

Anästhesie-Reservoirbeutel (ISO 5362:2000, modifiziert)

Ballons réservoirs d'anesthésie (ISO 5362:2000, modifiée)

Ta slovenski standard je istoveten z: **EN 1820:2005/prA1**

ICS:

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

SIST EN 1820:2005/kprA1:2009 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 1820:2005

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January 2009

ICS 11.040.10

English Version

Anaesthetic reservoir bags (ISO 5362:2000, modified)

Ballons réservoirs d'anesthésie (ISO 5362:2000, modifiée) Anästhesie-Reservoirbeutel (ISO 5362:2000, 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 1820:2005. 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

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Foreword

This document (EN 1820:2005/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 Addition of subclauses 4.7 – 4.9

Insert the following new subclauses:

"4.7 Usability

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.

4.8 Clinical evaluation

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

Check compliance by inspection of the risk management file.

4.9 Biophysical or modelling research

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

Check compliance by inspection of the technical file."

2 Modifications to 7.3

Add the following paragraphs:

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

NOTE 2: The attention of manufacturers is drawn to consistent use of indication across the Community for single use devices.”

Renumber the existing note as "NOTE 1".

3 Modification to 8

Add the following paragraph:

“The name and address of the authorized representative shall be given if the manufacturer does not have a registered place of business in the Community. The date of issue or the latest revision of the instructions for use shall be given."

4 Modifications to G.4

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

5 Modification to Table ZA

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**
4.3	7.5 (2nd paragraph)	
4.7	1 (2nd paragraph, 1st dash) (2nd paragraph, 2nd dash)	
4.8	6a)	
4.9	7.1 (3rd dash)	
7.3	13.6 (h)(2nd paragraph)	
7.3	13.3 (f)	
8	13.3 (a):	
8	13.6 (q)	
G.4	7.5 (2nd paragraph)	

"