SLOVENSKI STANDARD
SIST EN 1820:2000

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Dihalni baloni

Anaesthetic reservoir bags

Anästhesie-Reservoirbeutel

Ballons réservoirs d'anesthésie

Ta slovenski standard je istoveten z: **EN 1820:1997**

ICS:

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

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Descriptors: medical equipment, anaesthetic equipment, artificial breathing apparatus, rubber products, collapsible containers, specifications, capacity, design, dimensions, pressure resistance, tests, marking, graphic symbols

English version

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This European Standard was approved by CEN on 1997-01-27. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard has been prepared under a mandate given to CEN by the Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directives, see informative Annex ZA, which is an integral part of this standard.

This European Standard is based on the standard ISO 5362 "Anaesthetic reservoir bags" and differs from ISO 5362 primarily in that it contains methods of tests for leakage and for security of attachment of the necks of reservoir bags with 22 mm conical connectors.

This European Standard also differs from ISO 5362 in that the maximum pressure used in annex E for the pressure/volume test has been increased to 6,0 kPa (60 cm H_20). This is in line with current manufacturing practices of some manufacturers within Europe. It has traditionally been the view of the ISO Technical Committee responsible for ISO 5362 that the previous figure of 5,0 kPa (50 cm H_20) represented the maximum safe pressure that should be allowed in the event of an obstruction in the breathing system which prevents the release of expired gases.

Annexes A, B, C, D and E are normative and form part of this European Standard. Annexes F, G and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard is one of a series dealing with anaesthetic and respiratory equipment. This European Standard is primarily concerned with the design of the neck, size designation and resistance to pressure required to distend anaesthetic reservoir bags.

The requirement that reservoir bags should be electrically conductive when used with a flammable anaesthetic is widely recognized and is of particular importance when such bags are rhythmically compressed by the anaesthetist in order to provide intermittent positive pressure ventilation.

A small proportion of single use bags may leak slightly because of the manufacturing process. This standard therefore sets the maximum leakage rate allowed as 50 $ml.min^{-1}$.

A lower limit of 1 $ml.min^{-1}$ has been set for re-usable bags because leakage of such bags has a tendency to increase after repeated use.

Although anti-static bags are satisfactory for use with non-flammable anaesthetic agents, bags which are not anti-static can be employed in these circumstances. This standard therefore gives requirements for both types of bags.

Recommendations for materials are given in annex F.

1 Scope

This European Standard specifies requirements for reservoir bags for use with anaesthetic apparatus or lung ventilator breathing systems. It includes requirements for the design of the neck, size designation, distension and, where relevant, for electrical resistance.

Special-purpose bags, for example bellows and self-expanding bags, are excluded from the scope of this standard.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 556: 1994	Sterilization of medical devices - Requirements for medical devices to be labelled "STERILE"
prEN 868-1	Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods
EN 1281-1	Anaesthetic and respiratory equipment - conical connectors - Part 1 : Cones and sockets
EN 60601-1: 1990	Medical electrical equipment - Part 1 : General requirements for safety
ISO 468	Surface roughness - Parameters, their values and general rules for specifying requirements

3 Definitions

For the purpose of this European Standard the following definitions apply :

3.1 anaesthetic reservoir bag : Collapsible container from which the patient may draw a tidal volume [ISO 4135: 1995].

3.2 assembled neck : Neck incorporating an adaptor.

3.3 adaptor : Specialized connector to establish functional continuity between otherwise disparate or incompatible components, one end of which is intended to be inserted into the neck of the bag, the other end having a conical connector complying with EN 1281-1.

3.4 plain neck : Neck designed to fit directly over a male conical connector.

3.5 tail : Tubular extension of the bag at the end opposite to the neck.

4 Leakage

NOTE: For the purpose of this standard the flow of air required to maintain the specified internal gas pressure is assumed to equal the leakage rate.

4.1 Re-usable bags

When tested in accordance with annex A, bags intended for re-use shall not leak at a rate of more than 1 $ml.min^{-1}$.

4.2 Single use bags

When tested in accordance with annex A, bags intended for single use shall not leak at a rate of more than 50 $ml.min^{-1}$.

5 Size designation

The size of the bag shall be designated by the nominal capacity expressed in litres.

6 Capacity

The actual capacity of the bag when tested in accordance with annex B shall be the marked value subject to a tolerance of ± 15 %.

7 Design

7.1 Neck

7.1.1 Necks shall be either plain or assembled.

7.1.2 Assembled necks shall incorporate an adaptor (see figure 1) bearing a female conical connector in accordance with EN 1281-1.

NOTE: Plain necks can be reinforced internally or externally or made of a thicker material than that of the bag.

7.2 Tail

The tail, if provided, shall have a minimum length of 20 mm.

NOTE: Bags, especially those intended for paediatric anaesthesia, can have a tail.

7.3 Adaptor of the assembled neck

The adaptor of the assembled neck shall not become detached from the assembled neck when tested in accordance with annex C.

7.4 Neck to fit 22 mm connector

NOTE: Plain necks can be of sizes other than those which fit directly onto 22 mm connectors. Necks to fit 8,5 mm or 15 mm connectors will require adaptors to fit with 8,5 mm or 15 mm conical connectors complying with EN 1281-1.

7.4.1 A plain neck shall have an axial length of not less than 26 mm from its open end when measured in the unstretched condition.

NOTE: Plain necks can be constructed to engage with the recess at the base of a 22 mm male connector

7.4.2 Necks, whether plain or assembled, shall not become detached from a male connector when tested in accordance with annex D.