Irish Standard
I.S. EN 1820:2005+A1:2009

Anaesthetic reservoir bags (ISO 5362:2000, modified)

I.S. EN 1820:2005+A1:2009

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English Version

Anaesthetic reservoir bags (ISO 5362:2000, modified)

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

Anästhesie-Reservoirbeutel (ISO 5362:2000, geändert)

This European Standard was approved by CEN on 25 April 2005 and includes Amendment 1 approved by CEN on 16 July 2009.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

The text of the International Standard ISO 5362:2000 from Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) has been taken over as a European Standard by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI, with common modifications which are indicated by a straight line in the margin of the text.

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of an identical text or by endorsement, at the latest by February 2010 and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This European Standard was approved by CEN on 25 April 2005 and includes Amendment 1, approved by CEN on 16 July 2009.

This document supersedes [A1] EN 1820:2005 [A1].

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1] [A1].

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: 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.

Introduction

This European Standard is one of a series dealing with anaesthetic and respiratory equipment. This document 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 anaesthetic provider in order to provide intermittent positive-pressure ventilation.

This European Standard gives requirements for both antistatic and non-antistatic bags. Only antistatic bags are suitable for use with flammable anaesthetic agents.

This European Standard includes requirements for both single-use and reusable bags. Reusable bags are intended to comply with the requirements of this document for the recommended product life.

The reference test method given as Annex E is not practical for routine use in manufacturing control, because it involves filling the bag with water. For this reason, another test method using air rather than water has been provided for information in Annex F. This may ultimately be suitable as the reference test method if it can be shown to give results equivalent to Annex E.

A test method for leakage of bags using air rather than water is given as Annex A for information only. Recommendations for materials are given in Annex G.

1 Scope

This European Standard specifies requirements for antistatic and non-antistatic 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.

This document is not applicable to special-purpose bags, for example bellows and self-expanding bags. Bags for use with anaesthetic gas scavenging systems are not considered to be anaesthetic reservoir bags and are thus outside the scope of this document.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be labelled "STERILE"*

EN 980, *Graphical symbols for use in the labelling of medical devices*

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1:1988)*

EN ISO 4287, *Geometrical product specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters (ISO 4287:1997)*

EN ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets (ISO 5356-1:2004)*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 11607, *Packaging for terminally sterilized medical devices*

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1
anaesthetic reservoir bag
collapsible gas container which is a component in a breathing system

[EN ISO 4135:—]

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 ISO 5356-1

3.4
plain neck
neck designed to fit directly over a male conical connector complying with EN ISO 5356-1