SLOVENSKI STANDARD
SIST EN ISO 8836:2009

01-julij-2009

Nadomeģļ a:
SIST EN ISO 8836:2008

Aspiracijski katetri za ļ iģļ enje dihalnih poti (ISO 8836:2007, popravljena verzija 15. 3. 2008)

Suction catheters for use in the respiratory tract (ISO 8836:2007, corrected version 2008-03-15)

Absaugkatheter zur Verwendung im Atemtrakt (ISO 8836:2007, Korrigierte Fassung 2008-03-15)

Sondes d'aspiration pour les voies respiratoires (ISO 8836:2007, version corrigée 2008-03-15)

Ta slovenski standard je istoveten z: **EN ISO 8836:2009**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 8836:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8836

April 2009

ICS 11.040.25; 11.040.10

Supersedes EN ISO 8836:2008

English Version

Suction catheters for use in the respiratory tract (ISO 8836:2007, corrected version 2008-03-15)

Sondes d'aspiration pour les voies respiratoires (ISO 8836:2007, version corrigée 2008-03-15)

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

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Foreword

The text of ISO 8836:2007 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8836:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 document supersedes EN ISO 8836:2008.

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Endorsement notice

The text of ISO 8836:2007, corrected version 2008-03-15, has been approved by CEN as a EN ISO 8836:2009 without any modification.

INTERNATIONAL STANDARD

ISO 8836

Third edition
2007-09-01

Corrected version
2008-03-15

Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

Reference number
ISO 8836:2007(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 8836 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This third edition cancels and replaces the second edition (ISO 8836:1997) certain clauses of which have been technically revised. Suction catheters are now required to have more than one orifice, except when used in low vacuum systems or under direct vision. Material characteristics and requirements related to suction catheters were previously informative but are now normative to comply with the Essential Requirements of the Medical Device Directives. They have been moved from an informative annex to normative requirements in the body of the standard. Table 1 (colour identification) has been combined with Table 2 (metric dimensions).

This corrected version of ISO 8836 contains changes to the Normative references on page 1.

ISO 11607 has been replaced by ISO 11607-1 and ISO 11607-2. The reference in subclause 8.2.2 on page 6 has been altered.

Introduction

This International Standard specifies dimensions and requirements for suction catheters for use in the respiratory tract.

Size is designated by outside diameter which is important when selecting catheters because of its relationship to the ease with which the catheter can be passed through a tracheal or tracheostomy tube (see ISO 5361 for details of requirements for tracheal tubes and tracheostomy tubes).

Flammability of suction catheters, for example if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognised hazard[1)] that is addressed by appropriate clinical management and is outside the scope of this International Standard.

1) See ISO/TR 11991.