

Kopsuventilaatorid. Osa 4: Erinõuded käsiajamiga elustamisseadmetele

Lung ventilators - Part 4: Particular requirements for operator
- powered resuscitators

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10651-4:2009 sisaldab Euroopa standardi EN ISO 10651-4:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 29.05.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

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English Version

Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)

Ventilateurs pulmonaires - Partie 4: Exigences relatives aux ressuscitateurs à puissance motrice manuelle (ISO 10651-4:2002)

Lungenbeatmungsgeräte - Teil 4: Anforderungen an anwenderbetriebene Wiederbelebungsgeräte (Handbeatmungsgeräte) (ISO 10651-4:2002)

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Foreword

The text of ISO 10651-4:2002 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 10651-4:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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This document supersedes EN ISO 10651-4:2002.

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.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 10651-4:2002 has been approved by CEN as a EN ISO 10651-4:2009 without any modification.

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1 Scope

This European Standard specifies requirements for operator-powered resuscitators intended for use with all age groups and which are portable and intended to provide lung ventilation to individuals whose breathing is inadequate. Operator-powered resuscitators for infants and children are designated according to body mass range and approximate age equivalent.

Electrically- and gas-powered resuscitators are not covered by this European Standard.

NOTE Annex B contains rationale statements for this Part of this European Standard. The clauses and subclauses which have corresponding rationale statements are marked with **R)** after their number.

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 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 (including amendments).

EN 148-1, *Respiratory protective devices - Threads for facepieces –Part 1: Standard thread connection.*

EN 556: 1994+A1:1998, *Sterilization of medical devices - Requirements for terminally-sterilized medical devices to be labelled "STERILE".*

EN 737-1, *Medical gas pipeline systems - Part 1: Terminal units for compressed medical gases and vacuum.*

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods .*

EN 1041, *Information supplied by the manufacturer with medical devices.*

EN 1281-1, *Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets.*

prEN 13544-2:2000, *Respiratory therapy equipment – Part 2 : Specifications for tubing and connectors.*

EN ISO 4135:1996, *Anaesthesiology – Vocabulary (ISO 4135 :1995).*