Irish Standard
I.S. EN ISO 10651-4:2009

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

# I.S. EN ISO 10651-4:2009

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**I.S. EN ISO 10651-4:2009**

EUROPEAN STANDARD

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# EN ISO 10651-4

April 2009

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Supersedes EN ISO 10651-4:2002

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)

This European Standard was approved by CEN on 21 March 2009.

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This European Standard exists 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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EUROPÄISCHES KOMITEE FÜR NORMUNG

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# Contents

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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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 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.

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 the United Kingdom.

**Endorsement notice**

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

# Annex ZA
(Informative)

# Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

**Table ZA.1 – Correspondence between this European Standard and EU Directives**

| Clause(s)/sub-clause(s) of this EN | Essential Requirements (ERs) of Directive 93/42/EEC | Qualifying remarks/Notes |
|---|---|---|
| All | 1 (1st paragraph), 2 | |
| 4.1 | 3, 9.1 | |
| 4.2 | 3, 9.1 | |
| 4.3 | 3, 9.1 | |
| 4.4 | 9.1 | |
| 4.5 | 3, 9.1 | |
| 4.6 | 3, 7.1, 7.6, 9.1 | |
| 4.7 | 3, 7.3, 9.1 | |
| 4, 5, 9, 10 | 1 (2nd paragraph, 1st dash) | This relevant Essential Requirement is not fully addressed in this European Standard |
| 4, 5, 9, 10 | 1 (2nd paragraph, 2nd dash) | This relevant Essential Requirement is not fully addressed in this European Standard |
| - | 6a) | This relevant Essential Requirement is not addressed in this European Standard |
| 5.1 | 4, 9.2 | |
| 5.2 | 3, 4, 9.2 | |
| 5.3 | 3, 4, 7.6 | |
| 5.4 | 3, 4, 5 | |
| 5.5 | 4, 5 | |
| 5.7 | 7.5 (1st paragraph) | This relevant Essential Requirement is not fully addressed in this European Standard |

| Clause(s)/sub-clause(s) of this EN | Essential Requirements (ERs) of Directive 93/42/EEC | Qualifying remarks/Notes |
|---|---|---|
| 5.7 | 7.5 (2nd paragraph) | This relevant Essential Requirement is not fully addressed in this European Standard |
| - | 7.5 (3rd paragraph) | This relevant Essential Requirement is not addressed in this European Standard |
| 6.1 | 3, 9.1 | |
| 6.2 | 3, 9.2 | |
| 6.3 | 3, 9.2 | |
| 6.4 | 3, 9.1, | |
| 6.5 | 3, 7.5, 9.2 | |
| 6.6 | 3, 9.2 | |
| 6.7.1 | 3 | |
| 6.7.2 | 3, 9.2, 12.8.2 | |
| 7.1 | 3, 5, 9.2 | |
| 7.2 | 3, 9.2 | |
| 8.1 | 8.1, 8.3, 8.4, 8.5 | |
| 8.2 | 8.1, 8.3, 8.4, 8.5 | |
| 9 | 13.3 (a): | This relevant Essential Requirement is not fully addressed in this European Standard |
| 9.1 | 2, 6, 13.1, 13.2 | |
| 9.2 | 5, 9.2, 13.1, 13.2 | |
| 9.3 | 13.3, 13.4 | |
| 9, 10 | 13.3 (f) | This relevant Essential Requirement is not fully addressed in this European Standard |
| 9, 10 | 13.6 (h)(2nd paragraph) | This relevant Essential Requirement is not fully addressed in this European Standard |
| 10 | 9.3, 13.1, 13.2, 13.3, 13.4, 13.6 | |
| 10 | 13.6 (q) | This relevant Essential Requirement is not addressed in this European Standard |
| | All other requirements are not applicable to this standard | |

**WARNING**: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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I.S. EN ISO 10651-4:2009

INTERNATIONAL STANDARD

**ISO 10651-4**

First edition
2002-03-01

# Lung ventilators —

## Part 4: Particular requirements for operator-powered resuscitators

*Ventilateurs pulmonaires —*

*Partie 4 : Exigences relatives aux ressuscitateurs à puissance motrice manuelle*

Reference number
ISO 10651-4:2002(E)

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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 3.

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.

Attention is drawn to the possibility that some of the elements of this part of ISO 10651 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10651-4 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

ISO 10651 consists of the following parts, under the general title *Lung ventilators*:

— *Part 1: Requirements*

— *Part 2: Particular requirements for home care ventilators*

— *Part 3: Particular requirements for emergency and transport ventilators*

— *Part 4: Particular requirements for operator-powered resuscitators*

Annex A forms a normative part of this part of ISO 10651. Annex B is for information only.

For the purposes of this part of ISO 10651, the CEN annex regarding fulfilment of European Council Directives has been removed.

# Contents

# Foreword

This document (EN ISO 10651-4:2002) has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment".

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 September 2002, and conflicting national standards shall be withdrawn at the latest by September 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 EU Directive(s).

Annex A is normative and form part of this European Standard.

Annex B is 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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

# 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)*.

# 3 Terms and definitions

For the purposes of this part of EN ISO 10651, the terms and definitions given in EN ISO 4135:1996 and the following terms and definitions apply.

NOTE Some of the definitions have been taken from EN ISO 4135, but they are included in this European Standard for convenience; other definitions, which are given in EN ISO 4135, for apparatus in general, have been modified slightly for the purposes of this European Standard as they apply specifically to resuscitators.

**3.1**
**reverse leakage**
volume of expired gas which does not pass through the expiratory port but returns to the resuscitator

**3.2**
**bag inlet valve**
valve activated by the subatmospheric pressure in the compressible unit of the resuscitator to refill the compressible unit with gas at ambient pressure

**3.3**
**bag refill valve**
valve, with no manual trigger, activated by the sub-atmospheric pressure in the compressible unit of the resuscitator to refill the compressible unit from a pressurized gas source