

Institut luxembourgeois de la normalisation de l'accréditation, de la sécurité et qualité des produits et services

ILNAS-EN ISO 10651-6:2004

Lung ventilators for medical use Particular requirements for basic
safety and essential performance Part 6: Home-care ventilatory support

Beatmungsgeräte für die medizinische Anwendung - Besondere Festlegungen für die grundlegende Sicherheit einschließlich der wesentlichen

Ventilateurs pulmonaires à usage médical - Exigences particulières pour la sécurité de base et les performances essentielles - Partie 6: Dispositifs

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National Foreword

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Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices (ISO 10651-6:2004)

Ventilateurs pulmonaires à usage médical - Exigences particulières pour la sécurité de base et les performances essentielles - Partie 6: Dispositifs d'assistance respiratoire à domicile (ISO 10651-6:2004)

This European Standard was approved by CEN on 21 June 2004.

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Foreword

This document (EN ISO 10651-6:2004) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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of an identical text or by endorsement, at the latest by January 2005, and conflicting national standards shall be withdrawn at the latest by January 2005.

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.

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Endorsement notice

The text of ISO 10651-6:2004 has been approved by CEN as EN ISO 10651-6:2004 without any modifications.

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.

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 normative 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.

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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Ventilateurs pulmonaires à usage médical — Exigences particulières pour la sécurité de base et les performances essentielles —

Partie 6: Dispositifs d'assistance respiratoire à domicile



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