

SLOVENSKI STANDARD
SIST EN ISO 10651-6:2009

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SIST EN ISO 10651-6:2005

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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)

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Beatmungsgeräte für die medizinische Anwendung - Besondere Festlegungen für die grundlegende Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Teil 6: Heimbeatmungsgeräte zur Atemunterstützung (ISO 10651-6:2004)

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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 (ISO 10651-6:2004)

Ta slovenski standard je istoveten z: EN ISO 10651-6:2009**ICS:**

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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SIST EN ISO 10651-6:2009**en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10651-6

April 2009

ICS 11.040.10

Supersedes EN ISO 10651-6:2004

English Version

**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
essentiels - Partie 6: Dispositifs d'assistance respiratoire
à domicile (ISO 10651-6:2004)

Beatmungsgeräte für die medizinische Anwendung -
Besondere Festlegungen für die grundlegende Sicherheit
einschließlich der wesentlichen Leistungsmerkmale - Teil 6:
Heimbeatmungsgeräte zur Atemunterstützung (ISO 10651-
6:2004)

This European Standard was approved by CEN on 14 March 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

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.

CEN members are the national standards bodies of 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.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 10651-6:2004 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 10651-6:2009 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 10651-6:2004.

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.

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Endorsement notice

The text of ISO 10651-6:2004 has been approved by CEN as a EN ISO 10651-6:2009 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 Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4 (3.1)	4, 12.1	
4 (3.4)	2	
5.2	12.6	
6.1	2, 13.1	
6.1	7.5 (2 nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 e)	13.3 a)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 q)	13.3 k)	
6.1 aa), 6.1 bb)	13.2	
6.1 cc)	13.3i)	
6.1 dd)	13.3 i), 13.6 k)	
6.1 ee)	13.3 e)	
6.1 ff)	13.3 b), 13.3 f)	
6.1 ff)	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 ff) 2)	13.2	
6.1 ff) 3)	13.3 d), 13.5	
6.1 ff) 4)	13.3 a)	
6.1 ff) 5)	13.3 k)	
6.1 ff) 6)	13.3 c)	
6.1 ff) 8)	13.3 m)	
6.1 gg)	12.8.2, 13.2, 13.3 i)	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.1 hh)	8.7	
6.3	2, 10, 12.9	
6.6	12.7.4	
6.8	7.5 (3 rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	2, 9.1, 13	
6.8.2 d)	13.6 a), 13.6 h), 13.6 i)	
6.8.2 d)	13.6 (h)(2 nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2 aa) 1)	13.4	
6.8.2 aa) 2)	13.6 c)	
6.8.2 aa) 4), 6.8.2 aa) 5), 6.8.2 aa) 6)	12.2, 13.6 d)	
6.8.2 aa) 7), 6.8.2 aa) 8)	12.2, 13.6 a)	
6.8.2 aa) 9)	13.6 p)	
6.8.2 aa) 10)	13.6 l)	
6.8.2 aa) 11)	13.6 b)	
6.8.2 aa) 12), 6.8.2 aa) 13), 6.8.2 aa) 14), 6.8.2 aa) 15), 6.8.2 aa) 16)	13.6 a)	
6.8.2 aa) 15), 6.8.2 aa) 17)	13.6 d)	
6.8.3	2, 3, 9.1, 13	
6.101	10.2	
7.101	9.1, 12.8.1	
10	4, 5, 9.2	
19.4	12.6	
36	9.2, 12.5	
43.2	7.3, 9.3	
44.3	7.6	
44.7	8.1	
44.8	7.1, 7.5	
44.8	7.5 (1 st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
46	10.2	
49.101	12.2	
49.102	4, 9.2, 12.1	
49.103	5, 9.2, 12.9	
51.101	4, 9.2	
51.102	6, 10.1	
51.103	10.1, 12.4, 12.8.2	
51.104	10.1, 12.4	
51.105	12.4, 12.8.2	
52.5	2, 12.1	
54.3	5, 9.2, 12.9	
56.3	12.7.4	
56.101	9.1, 12.8.1	
57.3	2, 4, 12.1, 12.8.1	

EN ISO 10651-6:2009 (E)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
101	12.4, 12.8.2	
-	6a)	This relevant Essential Requirement is not addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard

WARNING : Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR o 2006/42/EC	Qualifying remarks/Notes
-	1.1.4	This relevant EHSR is not addressed in this European Standard
6.1, 56	1.5.4	This relevant EHSR is not fully addressed in this European Standard
-	1.6.1	This relevant EHSR is not addressed in this European Standard
-	1.6.2	This relevant EHSR is not addressed in this European Standard
-	1.6.3	This relevant EHSR is not addressed in this European Standard
-	3.6.2	This relevant EHSR is not addressed in this European Standard

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INTERNATIONAL
STANDARD

ISO
10651-6

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2004-07-01

**Lung ventilators for medical use —
Particular requirements for basic safety
and essential performance —**

Part 6:

Home-care ventilatory support devices

iTeh STANDARD PREVIEW

(standards.iteh.ai)

*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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