SLOVENSKI STANDARD
SIST EN ISO 10651-2:2009

01-julij-2009

Nadomeġļa:
SIST EN ISO 10651-2:2005

Pljuļni ventilatorji za uporabo v medicini - Posebne zahteve za osnovno varnost in bistvene lastnosti - 2. del: Ventilatorji za oskrbo od aparata odvisnih pacientov na domu (ISO 10651-2:2004)

Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651-2:2004)

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Beatmungsgeräte für die medizinische Anwendung - Besondere Festlegungen für die grundlegende Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Teil 2: Heimbeatmungsgeräte für vom Gerät abhängige Patienten (ISO 10651-2:2004)

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Ventilateurs pulmonaires à usage médical - Exigences particulières pour la sécurité de base et les performances essentielles - Partie 2: Ventilateurs pour soins à domicile pour patients dépendants (ISO 10651-2:2004)

Ta slovenski standard je istoveten z: **EN ISO 10651-2:2009**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 10651-2:2009 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10651-2

April 2009

ICS 11.040.10

Supersedes EN ISO 10651-2:2004

English Version

Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651-2:2004)

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This European Standard was approved by CEN on 14 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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Ref. No. EN ISO 10651-2:2009: E

SIST EN ISO 10651-2:2009

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 10651-2:2009
https://standards.iteh.ai/catalog/standards/sist/576a7b3e-5d1d-4b01-8b65-1d0733d0bba4/sist-en-iso-10651-2-2009

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Foreword

The text of ISO 10651-2:2004 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 10651-2:2009 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 10651-2:2004.

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.

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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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https://standards.iteh.ai/catalog/standards/sist/576a7b3e-5d1d-4b01-8b65-1d0733d0bba4/sist-en-iso-10651-2-2009

Endorsement notice

The text of ISO 10651-2:2004 has been approved by CEN as a EN ISO 10651-2:2009 without any modification.

SIST EN ISO 10651-2:2009

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 (2nd 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)	7.1, 7.2, 13.3 k)	
6.1 aa), 6.1 bb)	9.2, 13.2	
6.1 cc)	13.3 i)	
6.1 dd)	13.3 i), 13.6 k)	
6.1 ee)	13.3 e)	
6.1 ff)	13.3 b), 13.3 f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 ff)	13.6 (h)(2nd paragraph)	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)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 ff) 5)	13.3 k)	

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SIST EN ISO 10651-2:2009
https://standards.iteh.ai/catalog/standards/sist/576a7b3e-5d1d-4b0f-8685-1d0731d3bba4/sist-en-iso-10651-2-2009

SIST EN ISO 10651-2:2009

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.1 ff) 6)	13.3 c)	
6.1 ff) 8)	13.3 m)	
6.1 gg)	8.2, 12, 13.2, 13.3 i)	
6.1 hh)	8.7	
6.3	2, 10, 12.9	
6.6	12.7.4	
6.8.2	2, 9.1, 13	
6.8.2	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2 d)	13.6 a), 13.6 h), 13.6 i)	
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), 6.8.2 aa) 17),	13.6 a)	
6.8.2 aa) 15), 6.8.2 aa) 18)	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	7.3, 9.3	
44.3	7.6	
44.7	8.1	
44.8	7.1, 7.5	
44.8	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
46	10.2	
49.101	9.2, 12.2, 12.3	
49.102	9.2	
49.103	4, 9.2, 12.1	
49.104	5, 9.2, 12.9	

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(standards.iteh.ai)
SIST EN ISO 10651-2:2009
https://standards.iteh.ai/catalog/standards/sist/576a7b3e-5d1d-4b01-8b65-1d0733d0bba4/sist-en-iso-10651-2-2009

SIST EN ISO 10651-2:2009

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
51.101	12.8.1. 12.8.2	
51.102	4, 9.2, 12.8.1	
51.103	4, 9.2, 12.8.1	
51.104	6, 10.1, 12.4	
51.105	12.4	
51.106	10.1, 12.4, 12.8.2	
51.107	12.4, 12.8.2	
51.108	12.4, 12.8.2	
51.109	10.1, 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	
56.102	9.1, 12.7.5	
56.103	9.1, 10.1, 10.2	
56.104	9.1, 10.1, 10.2	
56.105	9.1, 10	
57.3	2, 4, 12.1, 12.8.1	
201.8.3	12.4, 12.8.2	
201.12	5, 12.4	
-	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

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SIST EN ISO 10651-2:2009
https://standards.iteh.ai/catalog/standards/sist/576a7b3e-5d1d-4b01-8b65-1d0f33d0bba4/sist-en-iso-10651-2-2009

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

SIST EN ISO 10651-2:2009

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 of 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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SIST EN ISO 10651-2:2009
https://standards.iteh.ai/catalog/standards/sist/576a7b3e-5d1d-4b01-8b65-1d0733d0bba4/sist-en-iso-10651-2-2009

SIST EN ISO 10651-2:2009

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SIST EN ISO 10651-2:2009
https://standards.iteh.ai/catalog/standards/sist/576a7b3e-5d1d-4b01-8b65-1d0733d0bba4/sist-en-iso-10651-2-2009

SIST EN ISO 10651-2:2009

INTERNATIONAL STANDARD

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SIST EN ISO 10651-2:2009
https://standards.iteh.ai/catalog/standards/sist/576a7b3e-5d1d-4b01-8b65-1d0733d0bba4/sist-en-iso-10651-2-2009

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SIST EN ISO 10651-2:2009

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 10651-2:2009
https://standards.iteh.ai/catalog/standards/sist/576a7b3e-5d1d-4b01-8b65-1d0733d0bba4/sist-en-iso-10651-2-2009

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